Programa de Actualización en
Salud Pública y Epidemiología

18 edición
Verano 2013

Instituto Nacional
de Salud Pública

IIIª MESA REDONDA: REGULACIÓN DE DECLARACIONES DE PROPIEDADES SALUDABLES: La situación en Europa.

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Desde 1969 la OMS está interesada en analizar las regulaciones nacionales en salud. En 2004 resumió la situación de las declaraciones en el etiquetado

INTERNATIONAL HEALTH REGULATIONS (1969)

adopted by the Twenty-second World Health Assembly in 1969 and amended by the Twenty-sixth World Health Assembly in 1973 and the Thirty-fourth World Health Assembly in 1981

THIRD ANNOTATED EDITION

WORLD HEALTH ORGANIZATION
GENEVA
1983

Third annotated edition 1983
Updated and reprinted 1992, 1995

ISBN 92 4 158007 0

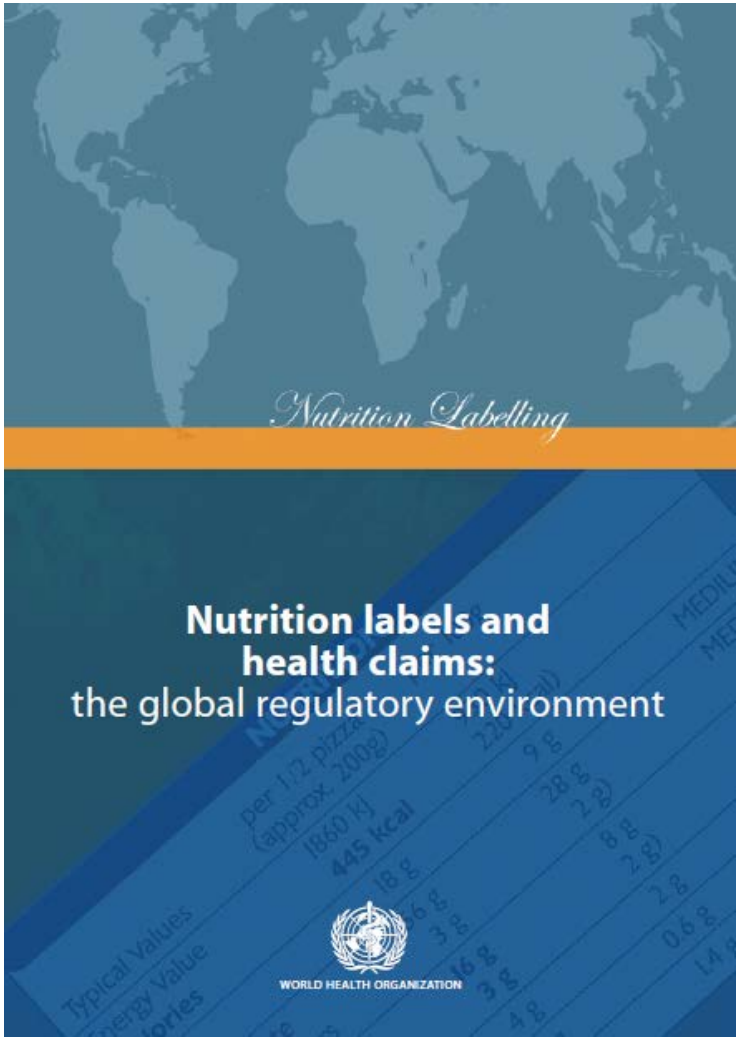


Table 2

Health claims regulations in 74 countries and areas, by category

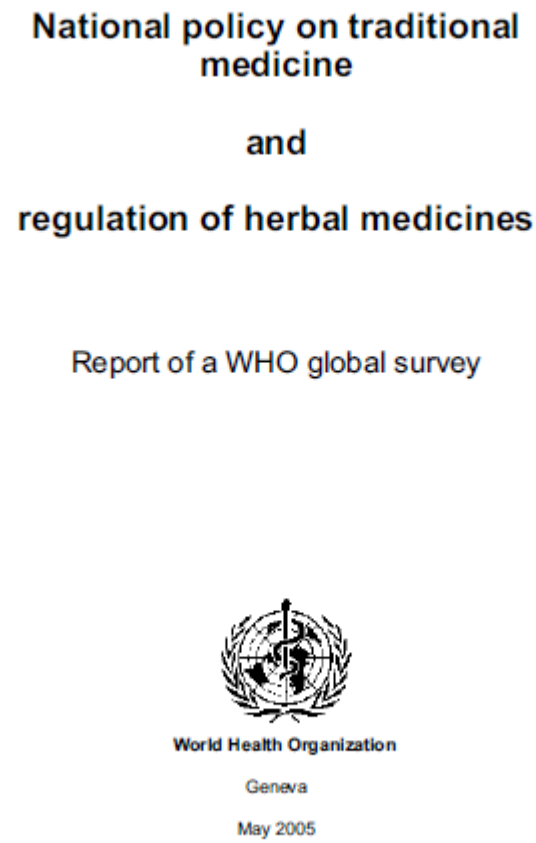
Claims making reference to disease are specifically prohibited	Specified disease risk-reduction claims are permitted	Nutrient function and/or other function claims are permitted	Specific framework to permit product-specific health claims	No regulations specific to health claims
Australia [a]	Brazil	Brazil	Japan [f]	Argentina
Austria [b]	Canada [g]	Canada [g]	Netherlands [h]	Bahamas
Belgium [c, h, q]	China	China	Sweden [h]	Bahrain
Brunei Darussalam	Indonesia	Belgium [h]		Bangladesh
Costa Rica [c,p]	Philippines	Denmark		Barbados [a]
Denmark	Sweden [h]	Finland		Belize
Ecuador [c]	United States	France [h]		Bermuda
Finland [d]		Germany		Bosnia and Herzegovina
France [h]		Greece		Botswana
Germany [e]		India [i]		Dominican Republic
Greece		Italy		Chile
Honduras [c]		Japan [f]		Croatia [d]
Israel [a]		Malaysia		Egypt
Italy		Poland [j]		El Salvador
Japan [f]		Netherlands [h]		Guatemala
Luxembourg		Republic of Korea		Hong Kong, SAR [o]
Lithuania		Spain [h]		Hungary
Malaysia		Singapore		Jordan
Morocco		Sweden [h]		Kenya
Netherlands [c,h,q]		Thailand		Kuwait
New Zealand [a]		United Kingdom [h,n]		Mauritius [m]
Nigeria [c,p]		United States		Mexico
Portugal		Viet Nam [k]		Nepal
Republic of Korea				Netherlands Antilles
Singapore [c]				Oman
Spain [h]				Pakistan
Switzerland				Paraguay
Thailand				Peru
United Kingdom [h, n]				Qatar
Viet Nam [a,k]				Saudi Arabia
				South Africa [a]
				Turkmenistan
				United Arab Emirates
				Uruguay
				Venezuela

Table 4

Countries and areas with regulations on the use of health claims in advertising

Countries in which regulations on the use of health claims on food labels also apply to advertising	Countries or areas in which advertising regulation covers health claims in some form	
Australia Brazil Canada Israel (yet to be implemented) Netherlands New Zealand Sweden United Kingdom	Brazil (self-regulation) Canada (self-regulation) China (law) Denmark (law) France (self-regulation and health law) India (law) Ireland (self-regulation) Italy (self-regulation) Japan (self-regulation) Hong Kong SAR (advertising law and health law)	Malaysia (law) Nigeria (law) Romania (law) Singapore (self-regulation) South Africa (self-regulation) Thailand (law) United Kingdom (law and self-regulation) United States (law)

Un campo todavía “gris”: La regulación botánica


National policy on traditional medicine

and

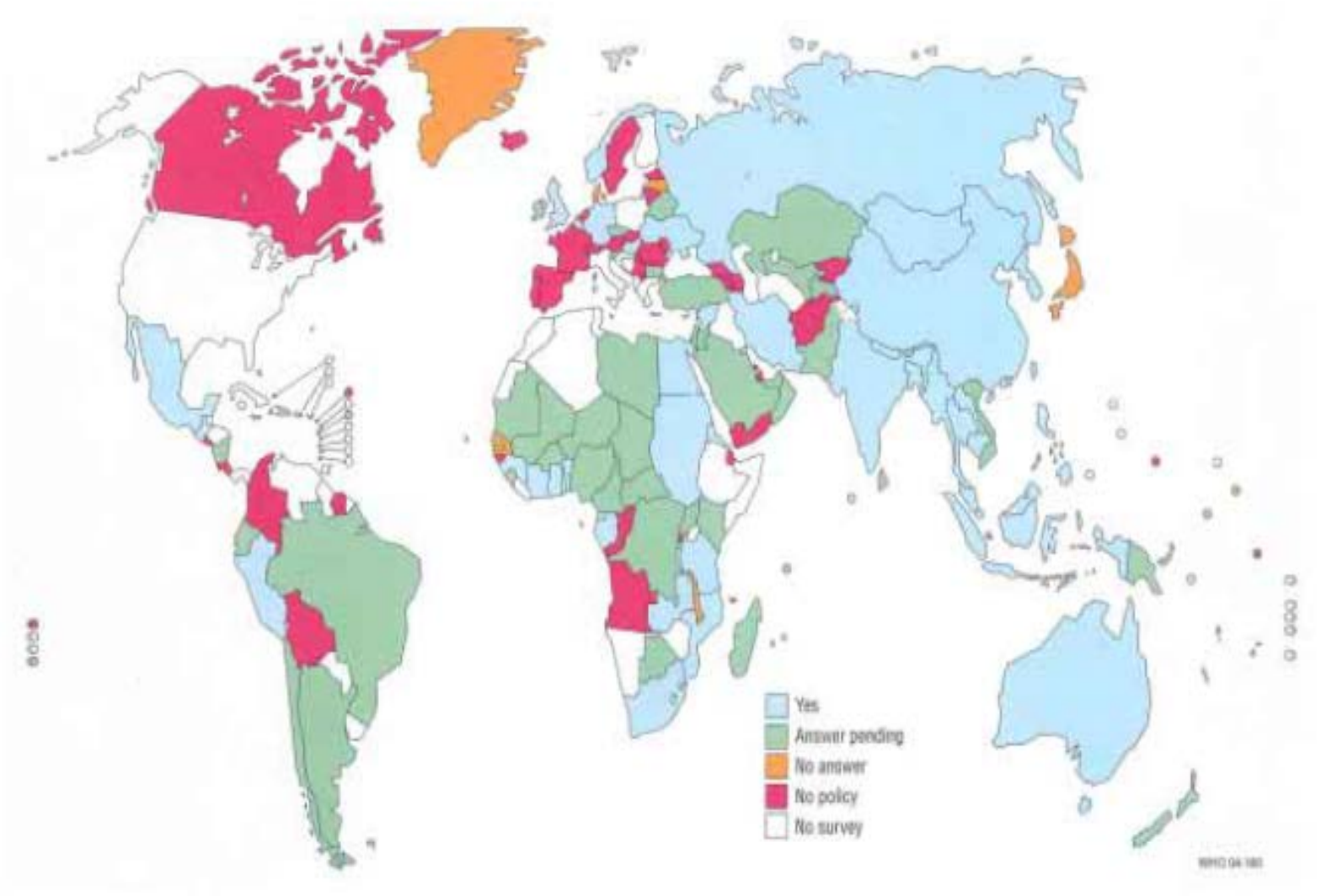
regulation of herbal medicines

Report of a WHO global survey

World Health Organization

Geneva

May 2005



Map 2. Member States with national policies and those pending

La primera Norma: Japón, 1998

FNFC

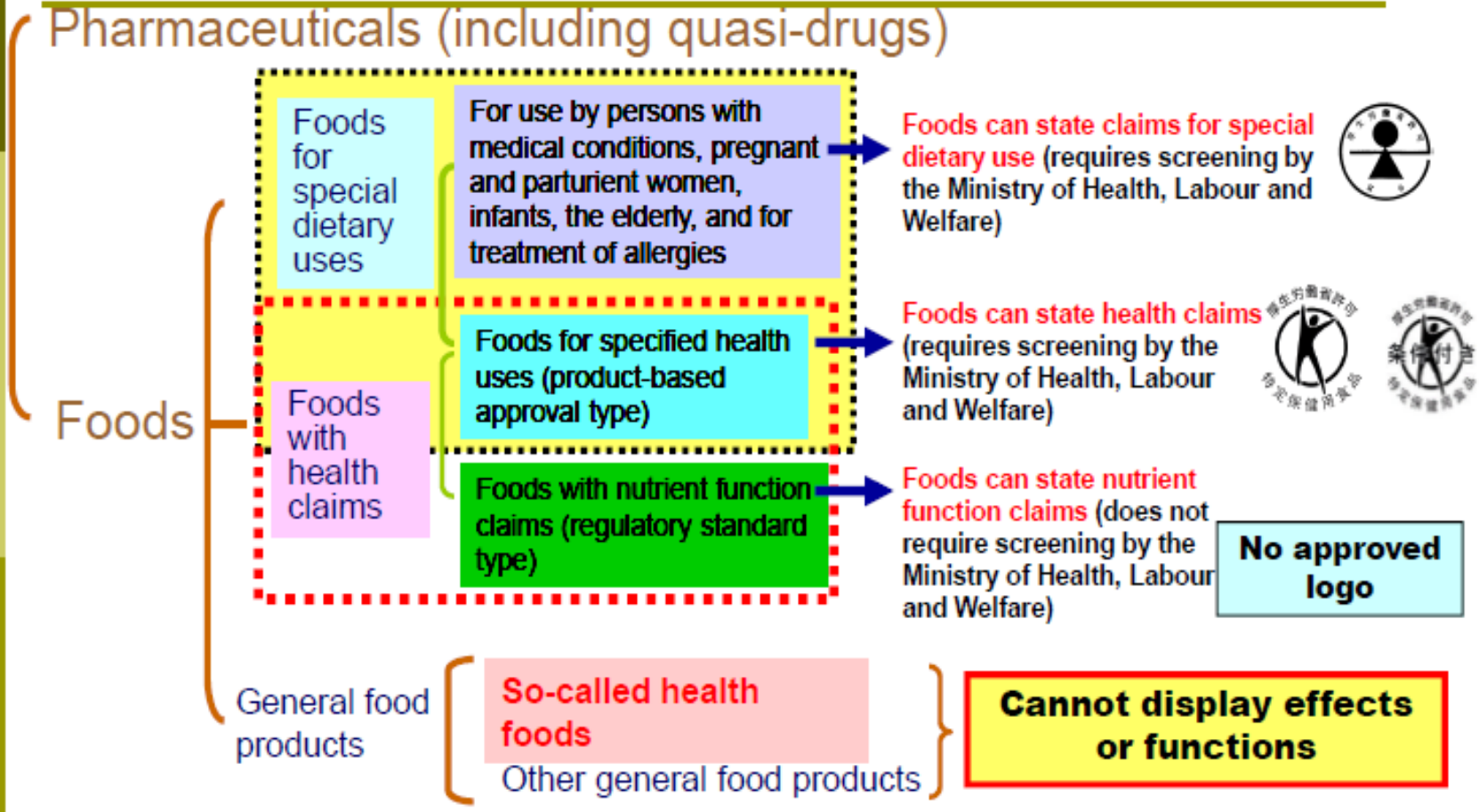
Foods with Nutrient Function Claims

FOSHU

Foods with Special Health Uses

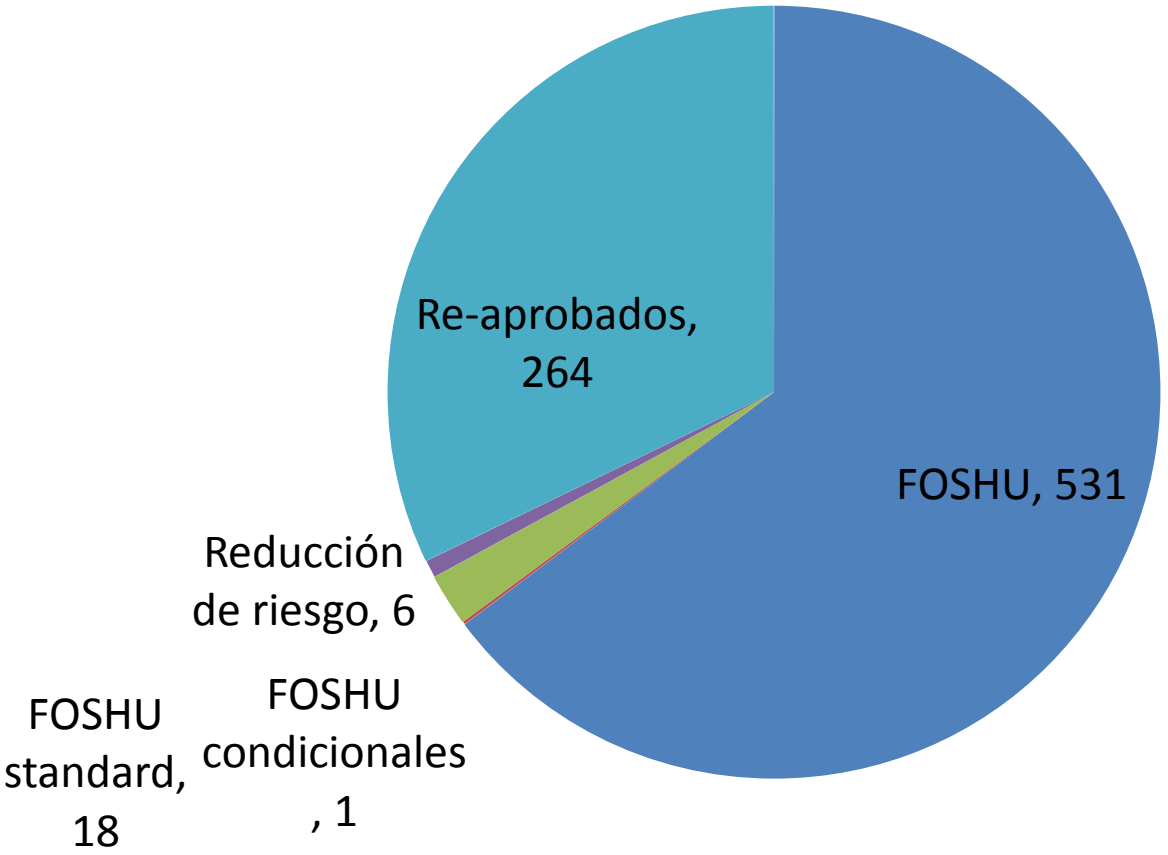
Foods with Health Claims

Categories of Foods Classified by Use

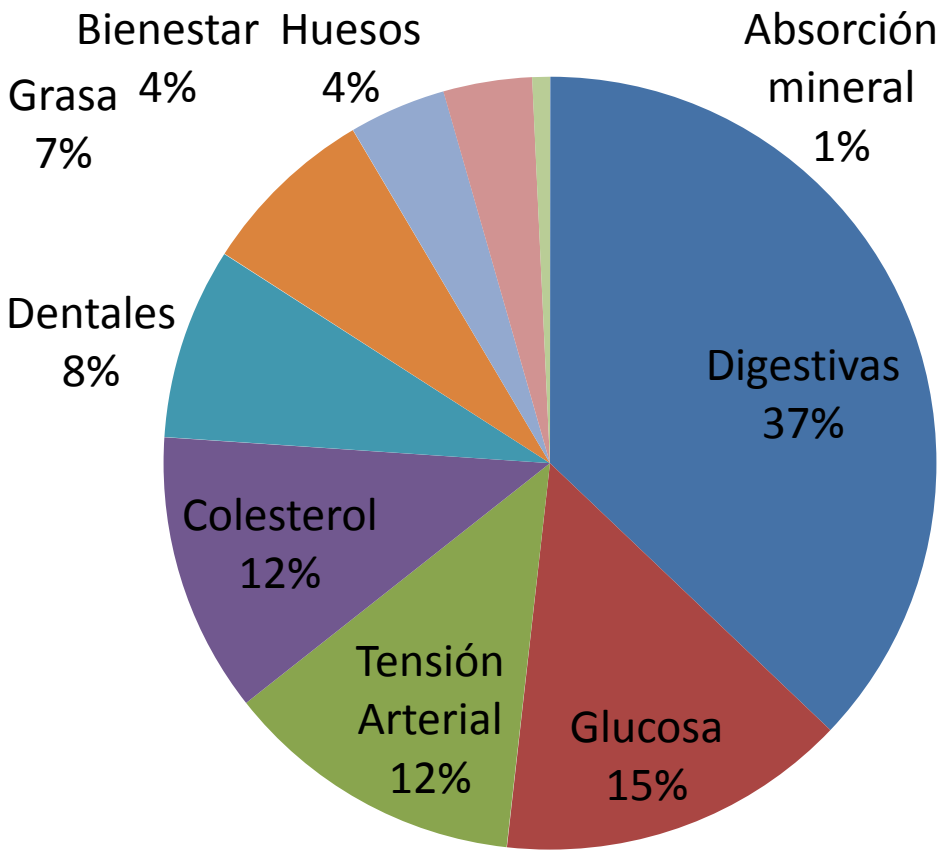


"Health Foods" = Foods with Health Claims + So-Called Health Foods

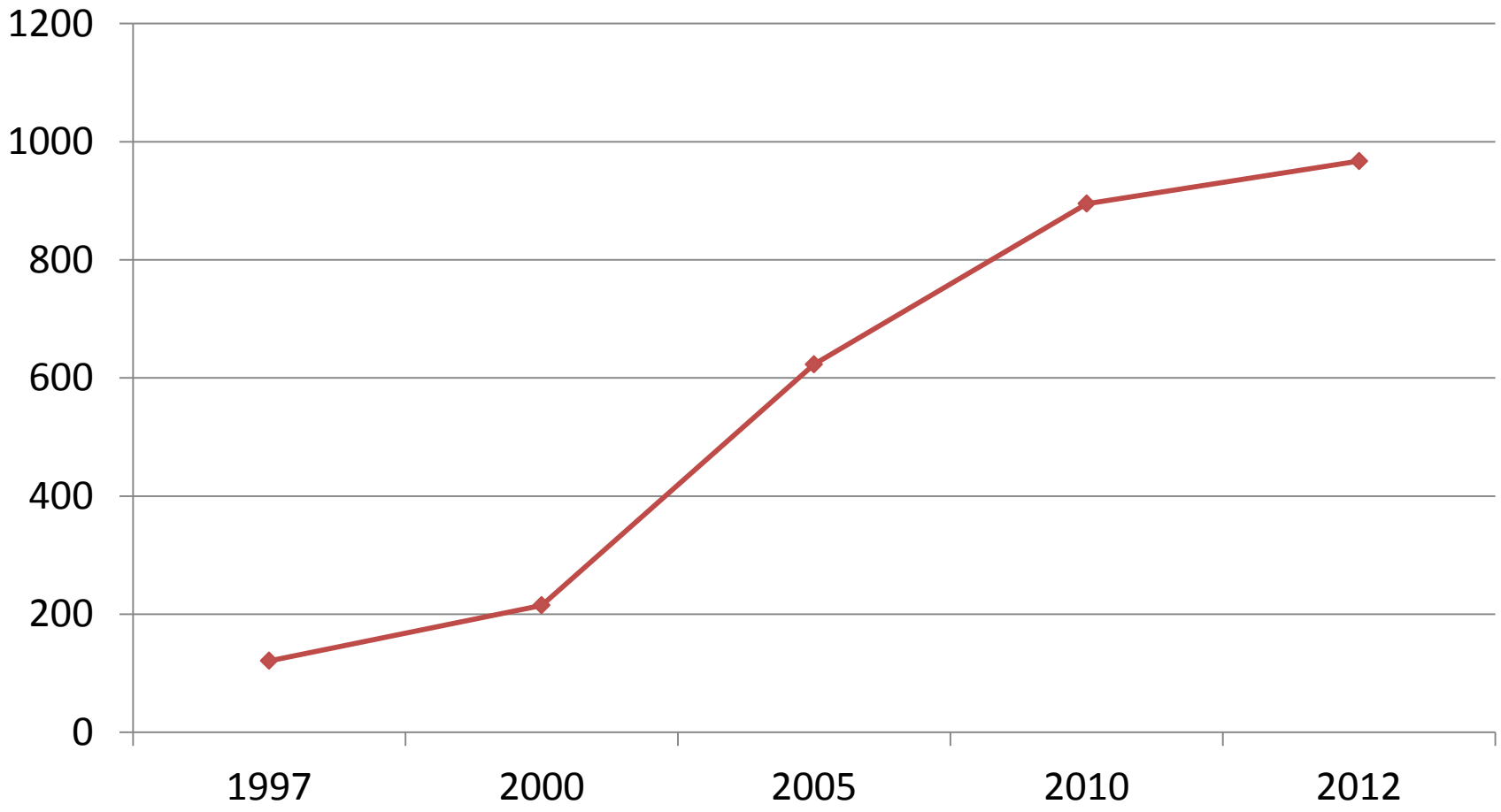
Categorías de alimentos aprobados (820)



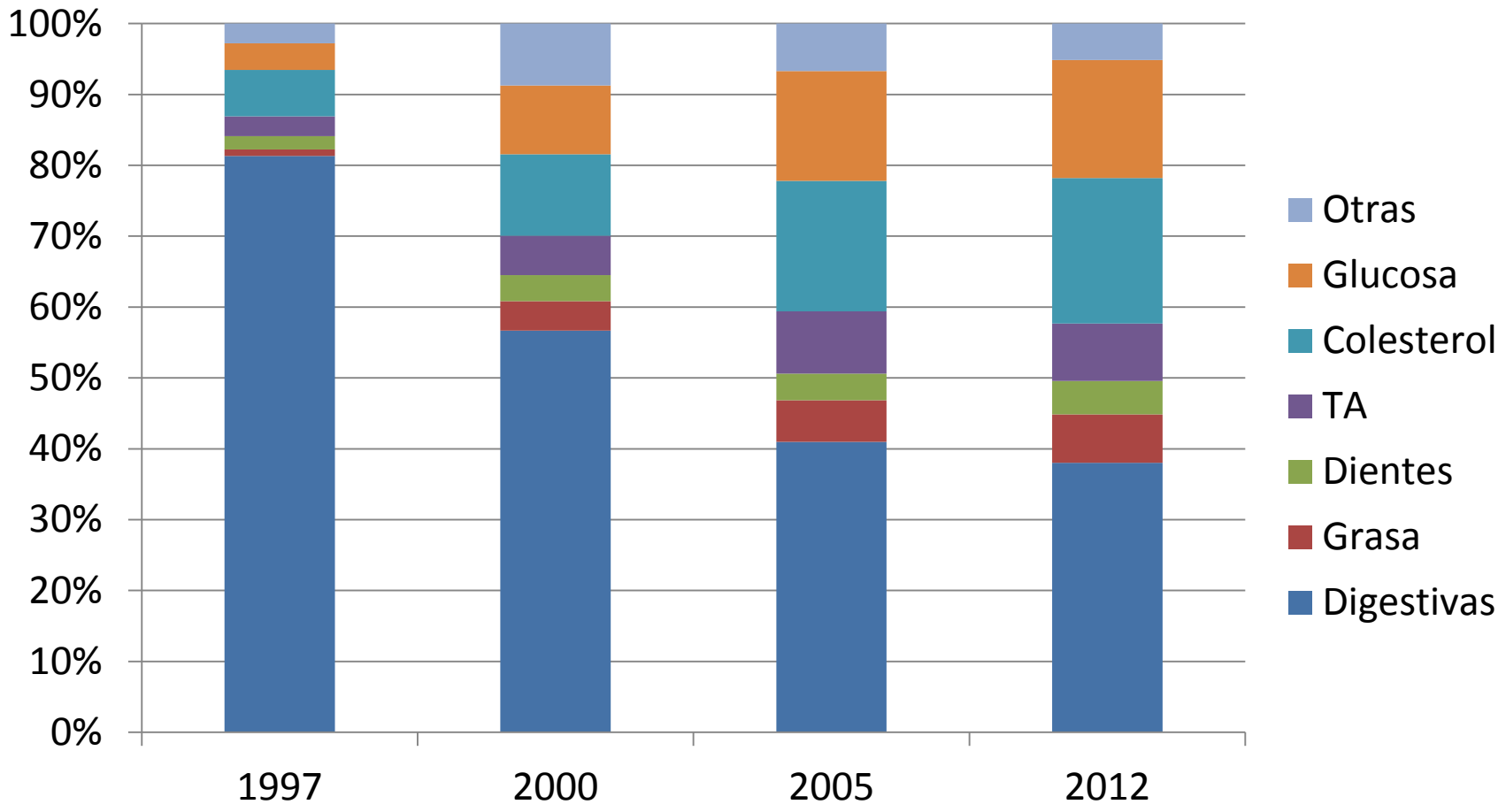
Declaraciones aprobadas



Mercado de alimentos con declaraciones en Japón (billones de Yenes)

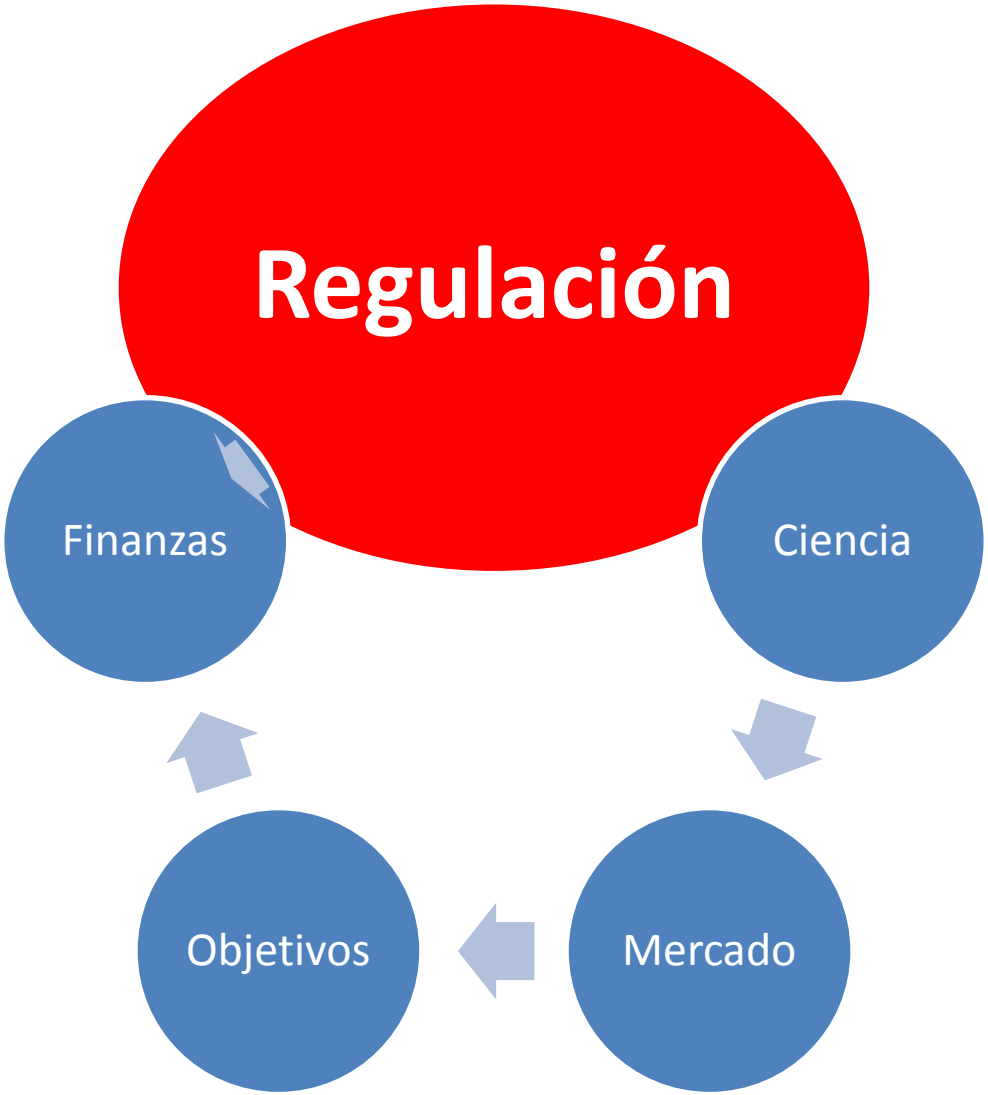


Evolución de los tipos de declaraciones de salud aprobadas




PLEASE, CAN YOU BE SLIGHTLY MORE SPECIFIC ?!?!..
EFSA health claims
FOOD IS GOOD

La regulación se convierte en el punto clave de los nuevos lanzamientos



Desarrollo del Reglamento 1924/2006

2001
- Propuesta de COM de un documento de discusión

2003
- COM desarrolla una propuesta de Reglamento

2005
- Mayo: Parlamento Europeo, primera lectura
- Diciembre: Posición común del Consejo

2006
- Mayo: Parlamento Europeo, segunda lectura
- Diciembre: Reglamento adoptado

2007
- 19 Enero: Entrada en vigor
- 1 Julio: Aplicación

▶B ▶C1 REGLAMENTO (CE) Nº 1924/2006 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 20 de diciembre de 2006

relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos ◀

(DO L 404 de 30.12.2006, p. 9)

14 December 2007

GUIDANCE ON THE IMPLEMENTATION OF REGULATION N° 1924/2006 ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

REGLAMENTO (CE) Nº 353/2008 DE LA COMISIÓN

de 18 de abril de 2008

por el que se establecen normas de desarrollo para las solicitudes de autorización de declaraciones de propiedades saludables con arreglo al artículo 15 del Reglamento (CE) nº 1924/2006 del Parlamento Europeo y del Consejo

(Texto pertinente a efectos del EEE)

REGLAMENTO (CE) Nº 1169/2009 DE LA COMISIÓN

de 30 de noviembre de 2009

que modifica el Reglamento (CE) nº 353/2008, por el que se establecen normas de desarrollo para las solicitudes de autorización de declaraciones de propiedades saludables con arreglo al artículo 15 del Reglamento (CE) nº 1924/2006 del Parlamento Europeo y del Consejo

(Texto pertinente a efectos del EEE)

Objetivos del Reglamento

PARA EL CONSUMIDOR:

Información veraz: Todo lo declarado avalado científicamente.

Información completa: Permita elegir con libertad.

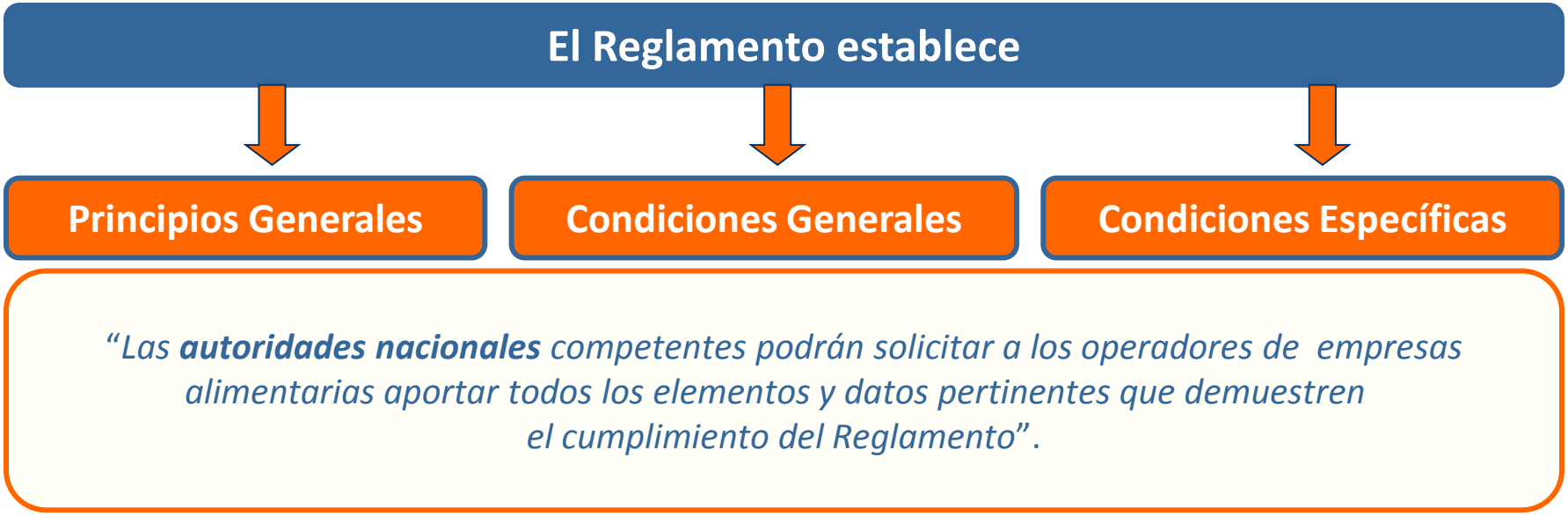
Información clara: Comprensible para el consumidor medio.

PARA LA INDUSTRIA:

Orientar/Potenciar la inversión en I+D+i.

Protección frente a la competencia desleal

Oportunidad de mejorar el perfil nutricional de sus productos.


El Reglamento establece
Principios Generales
Condiciones Generales
Condiciones Específicas
"Las **autoridades nacionales** competentes podrán solicitar a los operadores de empresas alimentarias aportar todos los elementos y datos pertinentes que demuestren el cumplimiento del Reglamento".

Declaración

*"cualquier mensaje o representación que **no sea obligatorio** con arreglo a la legislación comunitaria o nacional, incluida cualquier forma de representación pictórica, gráfica o simbólica que **afirme, sugiera o dé a entender que un alimento posee unas características específicas**"*

Declaración Nutricional

"cualquier declaración que afirme, sugiera o dé a entender que un alimento posee propiedades nutricionales benéficas específicas con motivo de: a) el aporte energético (valor calórico) i) que proporciona, ii) que proporciona en un grado reducido o incrementado, o iii) que no proporciona, y/o de b) los nutrientes u otras sustancias i)que contiene, ii) que contiene en proporciones reducidas o incrementadas, o iii) que no contiene"

"lo que contiene el alimento"

Declaración de Propiedades Saludables

"cualquier declaración que afirme, sugiera o dé a entender que existe una relación entre una categoría de alimentos, un alimento o uno de sus constituyentes, y la salud"

"lo que hace el alimento"

Artículo 2
Definiciones

5) Se entenderá por **«declaración de propiedades saludables»** cualquier declaración que afirme, sugiera o dé a entender que existe una relación entre una categoría de alimentos, un alimento o uno de sus constituyentes, y la salud.

6) Se entenderá por **«declaración de reducción del riesgo de enfermedad»** cualquier declaración de propiedades saludables que afirme, sugiera o dé a entender que el consumo de una categoría de alimentos, un alimento o uno de sus constituyentes reduce significativamente un factor de riesgo de aparición de una enfermedad humana.

Las declaraciones de salud en el Reglamento

Health Claims

- Genéricos (13.1)
- Nueva ciencia (13.5)
- Niños (14)
- Reducción riesgo (14)

Condiciones de las declaraciones

Demostrado el efecto nutricional o fisiológico benéfico mediante pruebas científicas generalmente aceptadas

Presente o ausente nutriente en cantidad significativa

Forma asimilable por el organismo

Cantidad que debe razonablemente esperar que se consuma

Condiciones específicas de cada declaración

El consumidor medio debe comprender los efectos beneficiosos tal como se expresan en la declaración

No debe dar a entender que una dieta equilibrada y variada no puede proporcionar cantidades adecuadas de nutrientes en general .

Tipos de declaraciones

Declaraciones incluidas en el Artículo13.1

Basadas en evidencias científicas generalmente aceptadas sobre un efecto beneficiosos de los alimentos o componentes de los alimentos sobre las funciones fisiológicas

Declaraciones incluidas en Artículo 13.5 y 14

1. Basadas en nuevas evidencias científicas de efectos beneficiosos sobre el mantenimiento funciones fisiológicas con/sin derechos propiedad.

2. Reducción de un factor de riesgo de enfermedad.

3. Salud y desarrollo de niños

Qué no se puede declarar nunca?

1. Declaraciones que incumplan principios y condiciones generales (Art. 3 y 5).

2. Declaraciones expresamente prohibidas (Art. 12). Las referidas a:

a) Que la salud puede verse afectada si no se consume el alimento en cuestión.

b) Al ritmo o magnitud de la pérdida de peso.

c) Declaraciones de propiedades saludables genéricas sin la correspondiente específica (Art.10.3).

3. Declaraciones de prevención, tratamiento o curación de enfermedades humanas (Lo prohíbe la Norma de Etiquetado General) .

Condiciones específicas para Declaraciones Comparativas

Cf. Artículo 9 del Reglamento de Declaraciones

- la **comparación** se hace entre alimentos de la **misma categoría**
- se indicará la **diferencia en la cantidad del nutriente y/o valor energético**
- la comparación hace referencia a la **misma cantidad de alimento**
- no pueden hacerse declaraciones comparativas sobre **vitaminas y minerales**

Aspectos destacados

Considerando 9: Flexibilidad

"garantizar que las declaraciones de propiedades saludables sean veraces, claras, fiables y útiles ….cuando el texto tenga el mismo significado para los consumidores que el de una determinada declaración autorizada… estas declaraciones deben estar sujetas a las mismas condiciones de uso".

Considerando 17

La autorización de una declaración no implica autorización para la comercialización del ingrediente o alimento.

“Principios generales a respetar en la adaptación de la redacción de una declaración de propiedades saludables autorizada” Documento de trabajo EEMM-CM

GENERAL PRINCIPLES TO BE RESPECTED IF THE WORDING OF AN AUTHORISED HEALTH CLAIM IS ADAPTED.

RECOMMENDATIONS ELABORATED BY MEMBER STATES' EXPERTS WHO ATTEND THE EUROPEAN COMMISSION'S WORKING GROUP ON NUTRITION AND HEALTH CLAIMS

These general principles were presented for the first time at an informal meeting in Brussels on 19 June 2012. Experts from 17 Member States[1] met to discuss a common approach to advising food business operators (FBOs) about flexibility of wording for health claims. The recommendations in this document only relate to the general principles over which there was broad agreement. Discussions at the meeting took place in English therefore it is possible that the examples given in this document may need to be adapted for other languages.

These recommendations were agreed by Member States' experts in December 2012.

However, note that authorities in some Member States may have developed more detailed national recommendations on flexibility of wording.

Introduction

Recital (9) of Regulation 432/2012 states: "One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear, reliable and useful to the consumer. In that respect, the wording and presentation of such claims have to be taken into account. Where the wording of claims has the same meaning for consumers as that of an permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims." The terms and conditions of the EU Register of nutrition and health claims made on foods ("the Register") explain that some flexibility of wording is possible provided that its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population.

The aim of this document is to set out the principles that should be respected when authorised health claims are used but the wording used is not exactly as authorised. The same principles should be respected whenever authorised claims are used in commercial communications whether in labelling, presentation or advertising and in whatever medium including on websites, radio and television.

Recommendations

In general, we recommend that FBOs stick as closely as possible to the authorised wording of health claims. This should ensure that consumers are provided with appropriate information and it should help enforcement officers judge whether claims are being used in compliance with the law.

[1] Austria, Belgium, Denmark, Finland, France, Germany, Estonia, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden, United Kingdom.

PRINCIPIOS GENERALES DE FLEXIBILIDAD EN LA REDACCIÓN DE DECLARACIONES DE PROPIEDADES SALUDABLES

RECOMENDACIONES ELABORADAS POR LOS EXPERTOS DE LOS ESTADOS MIEMBROS QUE ASISTEN AL GRUPO DE TRABAJO DE LA COMISIÓN SOBRE DECLARACIOENS DE PROPIEDADES NUTRICIONALES Y SALUDABLES EN LOS ALIMENTOS.

Estos principios generales se presentaron por primera vez en una reunión informal el 19 de junio de 2012 en Bruselas. Expertos de 17 Estados Miembros[1] se reunieron para discutir un enfoque común con el fin de asesorar a los operadores de empresas alimentarias (OEA) acerca de la flexibilidad del texto de declaraciones de propiedades saludables. Las recomendaciones de este documento sólo se refieren a los principios generales sobre los cuales hubo un amplio acuerdo. Los debates de la reunión fueron en inglés por lo que es posible que los ejemplos que figuran en este documento puedan necesitar ser adaptados a otras lenguas.
Estas recomendaciones fueron acordadas por expertos de los Estados Miembros en diciembre de 2012.
Sin embargo, hay que tener en cuenta que las autoridades de algunos Estados Miembros pueden haber desarrollado recomendaciones nacionales más detalladas sobre la flexibilidad de la redacción.

Introducción

El considerando (9) del Reglamento 432/2012 establece: "Una de las finalidades del Reglamento (CE) Nº 1924/2006 es garantizar que las declaraciones de propiedades saludables sean veraces, claras, fiables y útiles para el consumidor. Este objetivo debe tenerse presente en la redacción y la presentación de las declaraciones.
Cuando el texto de las declaraciones tenga el mismo significado para los consumidores que el de una determinada declaración autorizada de propiedades saludables porque demuestra que existe la misma relación entre la salud y una categoría de alimentos, un alimento o uno de sus constituyentes, estas declaraciones deben estar sujetas a las mismas condiciones de uso que la declaración autorizada de propiedades saludables". Los términos y condiciones del Registro europeo de declaraciones nutricionales y de propiedades saludables hechas en alimentos ("el Registro") establecen que es posible una cierta flexibilidad en la redacción siempre que su objetivo sea ayudar a la comprensión del consumidor, teniendo en cuenta factores tales como las variaciones lingüísticas y culturales y la población a la que van destinadas.
El objetivo de este documento es establecer los principios que deberían ser respetados cuando se utilicen las declaraciones de salud autorizadas pero la redacción utilizada no sea exactamente la autorizada. Se deben respetar los mismos principios cuando se utilicen declaraciones autorizadas en comunicaciones comerciales ya sea en el etiquetado, presentación o publicidad y por cualquier medio incluyendo los sitios web, la radio y la televisión.

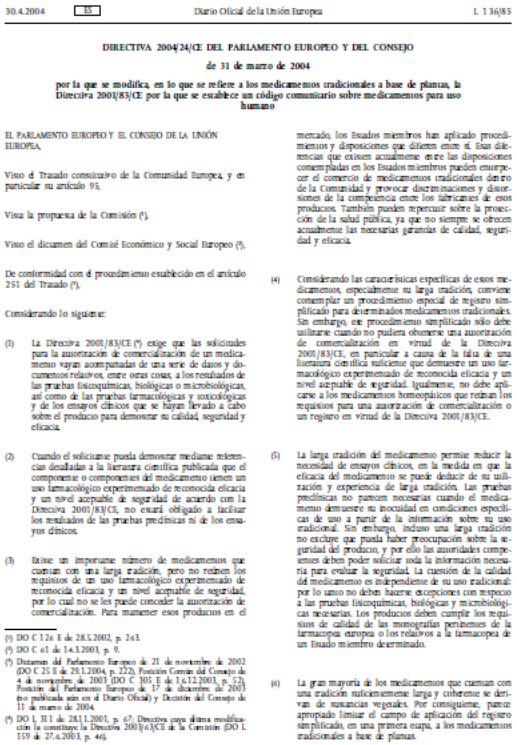
Recomendaciones

En general, recomendamos a los operadores de las empresas alimentarias (OEA) ceñirse lo más posible al texto autorizado para las declaraciones de propiedades saludables. Esto debería garantizar que los consumidores dispongan de información adecuada al tiempo que debería ayudar a las Autoridades competentes de juzgar si las declaraciones están siendo utilizadas de acuerdo con la ley.

[1] Austria, Bélgica, Dinamarca, Finlandia, Francia, Alemania, Estonia, Hungría, Irlanda, Lituania, Luxemburgo, Países Bajos, Noruega, Polonia, Portugal, Suecia y Reino Unido.

Especies botánicas

Directiva 2004/24: Seguridad



30.4.2004 ES Diario Oficial de la Unión Europea L 136/85

DIRECTIVA 2004/24/CE DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 31 de marzo de 2004

por la que se modifica, en lo que se refiere a los medicamentos tradicionales a base de plantas, la Directiva 2001/83/CE por la que se establece un código comunitario sobre medicamentos para uso humano

EL PARLAMENTO EUROPEO Y EL CONSEJO DE LA UNIÓN EUROPEA,

Visto el Tratado constitutivo de la Comunidad Europea, y en particular su artículo 95,

Vista la propuesta de la Comisión (1),

Visto el dictamen del Comité Económico y Social Europeo (2),

De conformidad con el procedimiento establecido en el artículo 251 del Tratado (3),

Considerando lo siguiente:

(1) La Directiva 2001/83/CE (4) exige que las solicitudes para la autorización de comercialización de un medicamento vayan acompañadas de una serie de datos y documentos relativos, entre otras cosas, a los resultados de las pruebas fisicoquímicas, biológicas o microbiológicas, así como de las pruebas farmacológicas y toxicológicas y de los ensayos clínicos que se hayan llevado a cabo sobre el producto para demostrar su calidad, seguridad y eficacia.

(2) Cuando el solicitante pueda demostrar mediante referencias detalladas a la literatura científica publicada que el componente o componentes del medicamento tienen un uso farmacológico experimentado de reconocida eficacia y un nivel aceptable de seguridad de acuerdo con la Directiva 2001/83/CE, no estará obligado a facilitar los resultados de las pruebas preclínicas ni de los ensayos clínicos.

(3) Existe un importante número de medicamentos que cuentan con una larga tradición, pero no reúnen los requisitos de un uso farmacológico experimentado de reconocida eficacia y un nivel aceptable de seguridad, por lo cual no se les puede conceder la autorización de comercialización. Para mantener esos productos en el mercado, los Estados miembros han aplicado procedimientos y disposiciones que difieren entre sí. Estas diferencias que existen actualmente entre las disposiciones contempladas en los Estados miembros pueden entorpecer el comercio de medicamentos tradicionales dentro de la Comunidad y provocar discriminaciones y distorsiones de la competencia entre los fabricantes de esos productos. También pueden repercutir sobre la protección de la salud pública, ya que no siempre se ofrecen actualmente las necesarias garantías de calidad, seguridad y eficacia.

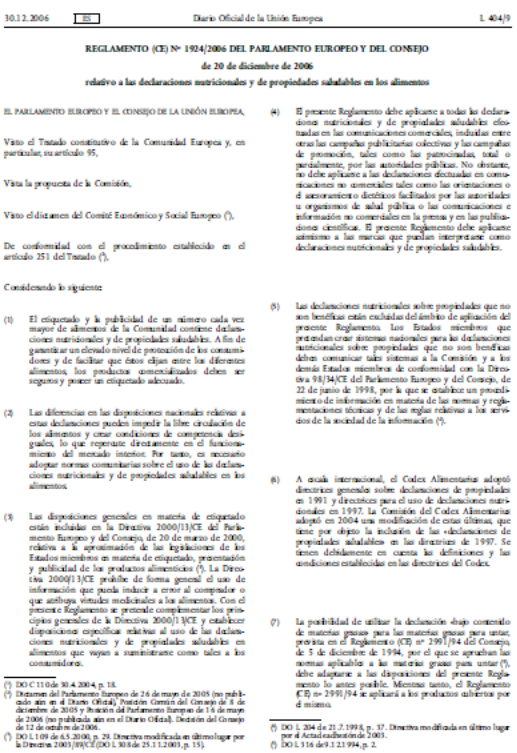
(4) Considerando las características específicas de estos medicamentos, especialmente su larga tradición, conviene contemplar un procedimiento especial de registro simplificado para determinados medicamentos tradicionales. Sin embargo, este procedimiento simplificado sólo debe utilizarse cuando no pudiera obtenerse una autorización de comercialización en virtud de la Directiva 2001/83/CE, en particular a causa de la falta de una fitoterapia científica suficiente que demuestre un uso farmacológico experimentado de reconocida eficacia y un nivel aceptable de seguridad. Igualmente, no debe aplicarse a los medicamentos homeopáticos que reúnan los requisitos para una autorización de comercialización o un registro en virtud de la Directiva 2001/83/CE.

(5) La larga tradición del medicamento permite reducir la necesidad de ensayos clínicos, en la medida en que la eficacia del medicamento se puede deducir de su utilización y experiencia de larga tradición. Las pruebas preclínicas no parecen necesarias cuando el medicamento demuestre su inocuidad en condiciones específicas de uso a partir de la información sobre su uso tradicional. Sin embargo, incluso una larga tradición no excluye que pueda haber preocupación sobre la seguridad del producto, y por ello las autoridades competentes deben poder solicitar toda la información necesaria para evaluar la seguridad. La cuestión de la calidad del medicamento es independiente de su uso tradicional: por lo tanto no deben hacerse excepciones con respecto a las pruebas fisicoquímicas, biológicas y microbiológicas necesarias. Los productos deben cumplir los requisitos de calidad de las monografías pertinentes de la farmacopea europea o los relativos a la farmacopea de un Estado miembro determinado.

(6) La gran mayoría de los medicamentos que cuentan con una tradición suficientemente larga y coherente se derivan de sustancias vegetales. Por consiguiente, parece apropiado limitar el campo de aplicación del registro simplificado, en una primera etapa, a los medicamentos tradicionales a base de plantas.

(1) DO C 126 E de 28.5.2002, p. 263.
(2) DO C 61 de 14.3.2003, p. 9.
(3) Dictamen del Parlamento Europeo de 21 de noviembre de 2002 (DO C 25 E de 28.1.2004, p. 222), Posición Común del Consejo de 4 de noviembre de 2003 (DO C 305 E de 16.12.2003, p. 52), Posición del Parlamento Europeo de 17 de diciembre de 2003 (no publicada aún en el Diario Oficial) y Decisión del Consejo de 11 de marzo de 2004.
(4) DO L 311 de 28.11.2001, p. 67. Directiva cuya última modificación la constituye la Directiva 2003/63/CE de la Comisión (DO L 159 de 27.6.2003, p. 46).

Reglamento 1924/2006: Función



30.12.2006 ES Diario Oficial de la Unión Europea L 404/9

REGLAMENTO (CE) Nº 1924/2006 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 20 de diciembre de 2006

relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos

EL PARLAMENTO EUROPEO Y EL CONSEJO DE LA UNIÓN EUROPEA,

Visto el Tratado constitutivo de la Comunidad Europea y, en particular, su artículo 95,

Vista la propuesta de la Comisión,

Visto el dictamen del Comité Económico y Social Europeo (1),

De conformidad con el procedimiento establecido en el artículo 251 del Tratado (2),

Considerando lo siguiente:

(1) El etiquetado y la publicidad de un número cada vez mayor de alimentos de la Comunidad contiene declaraciones nutricionales y de propiedades saludables. A fin de garantizar un elevado nivel de protección de los consumidores y de facilitar que éstos elijan entre los diferentes alimentos, los productos comercializados deben ser seguros y poseer un etiquetado adecuado.

(2) Las diferencias en las disposiciones nacionales relativas a estas declaraciones pueden impedir la libre circulación de los alimentos y crear condiciones de competencia desiguales, lo que repercute directamente en el funcionamiento del mercado interior. Por tanto, es necesario adoptar normas comunitarias sobre el uso de las declaraciones nutricionales y de propiedades saludables en los alimentos.

(3) Las disposiciones generales en materia de etiquetado están incluidas en la Directiva 2000/13/CE del Parlamento Europeo y del Consejo, de 20 de marzo de 2000, relativa a la aproximación de las legislaciones de los Estados miembros en materia de etiquetado, presentación y publicidad de los productos alimenticios (3). La Directiva 2000/13/CE prohíbe de forma general el uso de información que pueda inducir a error al comprador o que atribuya virtudes medicinales a los alimentos. Con el presente Reglamento se pretende complementar los principios generales de la Directiva 2000/13/CE y establecer disposiciones específicas relativas al uso de las declaraciones nutricionales y de propiedades saludables en alimentos que vayan a suministrarse como tales a los consumidores.

(4) El presente Reglamento debe aplicarse a todas las declaraciones nutricionales y de propiedades saludables efectuadas en las comunicaciones comerciales, incluidas entre otras las campañas publicitarias colectivas y las campañas de promoción, tales como las patrocinadas, total o parcialmente, por las autoridades públicas. No obstante, no debe aplicarse a las declaraciones efectuadas en comunicaciones no comerciales tales como las orientaciones o el asesoramiento dietéticos facilitados por las autoridades u organismos de salud pública o las comunicaciones e información no comerciales en la prensa y en las publicaciones científicas. El presente Reglamento debe aplicarse asimismo a las marcas que puedan interpretarse como declaraciones nutricionales y de propiedades saludables.

(5) Las declaraciones nutricionales sobre propiedades que no son beneficiarias están excluidas del ámbito de aplicación del presente Reglamento. Los Estados miembros que pretendan crear sistemas nacionales para las declaraciones nutricionales sobre propiedades que no son beneficiarias deben comunicar tales sistemas a la Comisión y a los demás Estados miembros de conformidad con la Directiva 98/34/CE del Parlamento Europeo y del Consejo, de 22 de junio de 1998, por la que se establece un procedimiento de información en materia de las normas y reglamentaciones técnicas y de las reglas relativas a los servicios de la sociedad de la información (4).

(6) A escala internacional, el Codex Alimentarius adoptó directrices generales sobre declaraciones de propiedades en 1991 y directrices para el uso de declaraciones nutricionales en 1997. La Comisión del Codex Alimentarius adoptó en 2004 una modificación de estas últimas, que tiene por objeto la inclusión de las «declaraciones de propiedades saludables» en las directrices de 1997. Se tienen debidamente en cuenta las definiciones y las condiciones establecidas en las directrices del Codex.

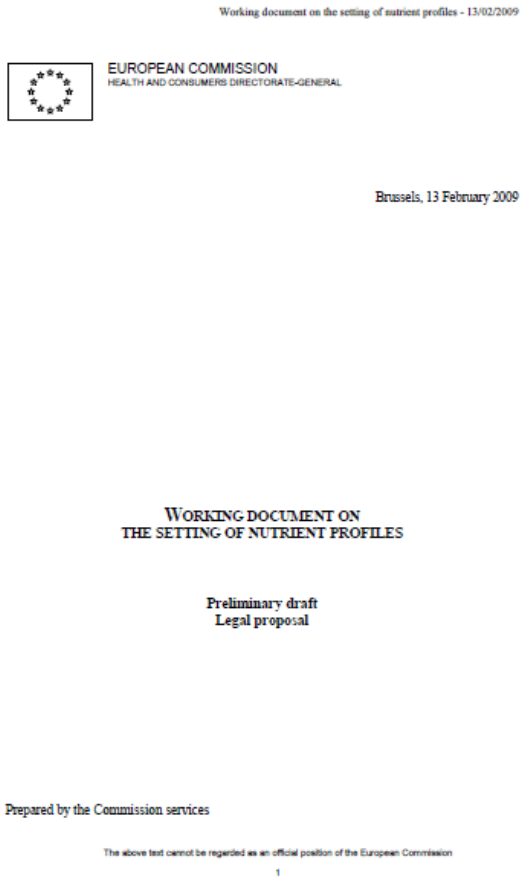
(7) La posibilidad de utilizar la declaración sobre contenido de materias grasas para las materias grasas para untar, prevista en el Reglamento (CE) nº 2991/94 del Consejo, de 5 de diciembre de 1994, por el que se aprueban las normas aplicables a las materias grasas para untar (5), debe adaptarse a las disposiciones del presente Reglamento lo antes posible. Mientras tanto, el Reglamento (CE) nº 2991/94 se aplicará a los productos ubicados por el mismo.

(1) DO C 110 de 30.4.2004, p. 18.
(2) Dictamen del Parlamento Europeo de 26 de mayo de 2005 (no publicado aún en el Diario Oficial), Posición Común del Consejo de 8 de diciembre de 2005 y Posición del Parlamento Europeo de 14 de mayo de 2006 (no publicada aún en el Diario Oficial). Decisión del Consejo de 12 de octubre de 2006.
(3) DO L 109 de 6.5.2000, p. 29. Directiva modificada en último lugar por la Directiva 2003/89/CE (DO L 308 de 25.11.2003, p. 15).
(4) DO L 204 de 21.7.1998, p. 37. Directiva modificada en último lugar por el Acta de adhesión de 2003.
(5) DO L 316 de 9.12.1994, p. 2.

Perfiles nutricionales

Artículo 4) Reglamento 1924/2006:

"las cantidades permitidas de determinados nutrientes y otras sustancias contenidas en los alimentos para que puedan realizar declaraciones".



Working document on the setting of nutrient profiles - 13/02/2009

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Brussels, 13 February 2009

WORKING DOCUMENT ON
THE SETTING OF NUTRIENT PROFILES

Preliminary draft
Legal proposal

Prepared by the Commission services

The above text cannot be regarded as an official position of the European Commission

1

ANNEX 1: specific nutrient profiles and conditions of use, which food or certain categories of food must comply with in order to bear nutrition or health claims

Food category		Specific conditions*	Thresholds		
			Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml except when specified otherwise)	Sugars (g/100g or 100ml)
Vegetable oils and spreadable fats as defined in Council Regulation (EC) No 2991/94		-	500	30 kcal /100g	-
Fruits, vegetables, seeds, and their products, except oils	Fruits, vegetables, and their products, except oils**	Minimum 50g of fruit and/or vegetable per 100g of finished products	400	5	15
	Seeds*** and their products, except oils	Minimum 50g of nuts per 100g of finished products	400	10	15
Meat or meat based products		Minimum 50g of meat per 100g of finished products	700	5	-
Fish, fishery products, crustaceans, and molluscs		Minimum 50g of fish per 100g of finished products	700	10	-
Dairy based products	Dairy based products, except cheeses	Minimum 50g of dairy constituents per 100g of finished products	300	2,5	15
	Cheeses	Minimum 50g of dairy constituents per 100g of finished products	600	10	15
Cereal and cereal products	Breads containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.	Minimum 50g of cereals per 100g of finished products	700 until [date of adoption + 6 years] 400 from [date of adoption + 6 years]	5	15
	Cereal and cereal products except breakfast cereals	Minimum 50g of cereals per 100g of finished products	400	5	15
	Breakfast cereals	Minimum 50g of cereals per 100g of finished products	500	5	25
Ready meals, soups and sandwiches		Minimum 200g per serving size Minimum 2 of the following for ready meals and sandwiches: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk	400	5	10
Non alcoholic beverages		Liquid foods, insofar as they do not qualify for one of the above mentioned food categories	-	-	8
Other foods		Solid foods, insofar as they do not qualify for one of the above mentioned food categories	300	2	10

* the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

** vegetables include potatoes, beans, and pulses.

*** seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.

COMMISSION IMPLEMENTING DECISION

of 24 January 2013

adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

(Text with EEA relevance)

(2013/63/EU)

Directrices para la aplicación de las condiciones específicas relativas a las declaraciones de propiedades saludables establecidas en el artículo 10 del Reglamento (CE) no 1924/2006

1. Prohibición de las declaraciones de propiedades saludables no autorizadas y de las declaraciones de propiedades saludables cuyo uso no se ajusta al Reglamento (artículo 10, apartado 1)

2. Información obligatoria que debe acompañar a las declaraciones de propiedades saludables autorizadas (artículo 10, apartado 2)

2.1. Distinción de tres casos para la aplicación del artículo 10, apartado 2

2.2. Cuatro elementos de información obligatoria:

a) Una declaración en la que se indique la importancia de una dieta variada y equilibrada y un estilo de vida saludable

b) La cantidad de alimento y el patrón de consumo requeridos para obtener el efecto benéfico declarado

c) En su caso, una declaración dirigida a las personas que deberían evitar el consumo del alimento, y

d) Una advertencia adecuada en relación con los productos que pueden suponer un riesgo para la salud si se consumen en exceso

3. Referencia a beneficios generales y no específicos (artículo 10, apartado 3)

ÁMBITO DE APLICACIÓN: "Todas las declaraciones nutricionales y de propiedades saludables efectuadas en las COMUNICACIONES COMERCIALES, en el etiquetado, la presentación o la publicidad de los alimentos que se suministren como tales al consumidor final"

-Las comunicaciones comerciales a los profesionales de la salud

-Las campañas publicitarias colectivas y de promoción (también las patrocinadas por autoridades públicas)

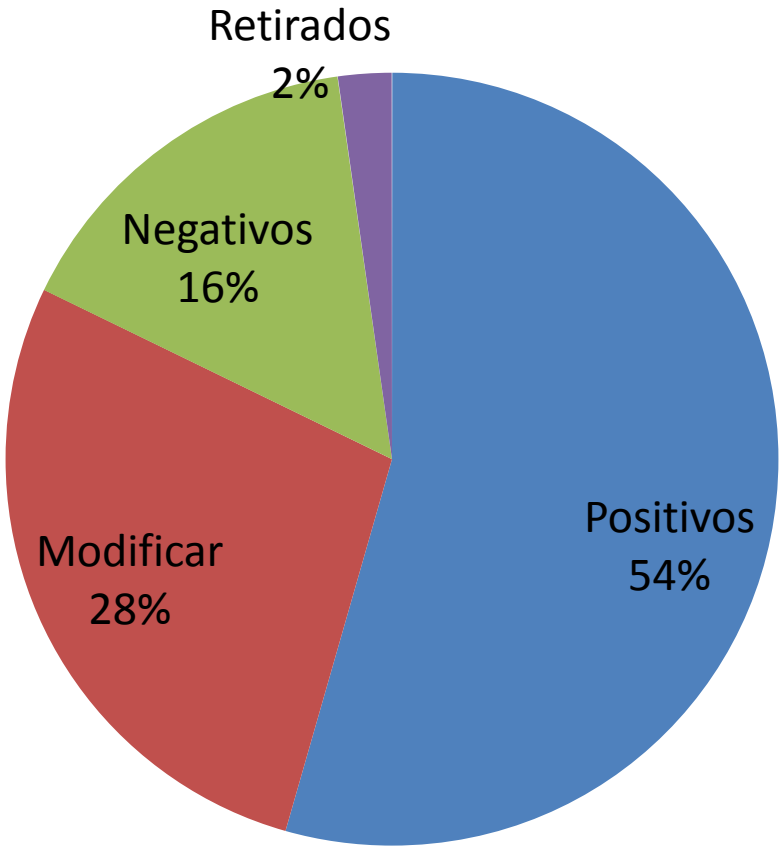
-Las marcas registradas, nombre comercial o denominación de fantasía

-Alimentos destinados a la restauración colectiva

Informes de asesoramiento previo o copy advice

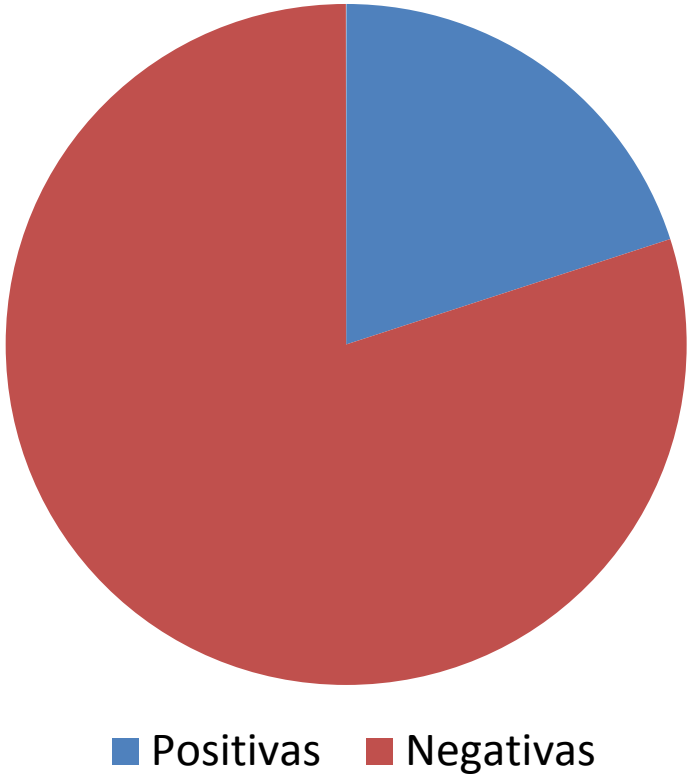
- Es un breve informe de asesoramiento sobre la corrección legal y ética de un determinado proyecto de campaña antes de su difusión al público.
- A solicitud del propio anunciante, de la agencia que tiene encomendada la realización de la campaña o su planificación o del medio que va a difundirla.
- Especialmente útil cuando se trata de publicidad a la que resulta aplicable una norma cuya interpretación resulta singularmente difícil.

Copy Advices 2012

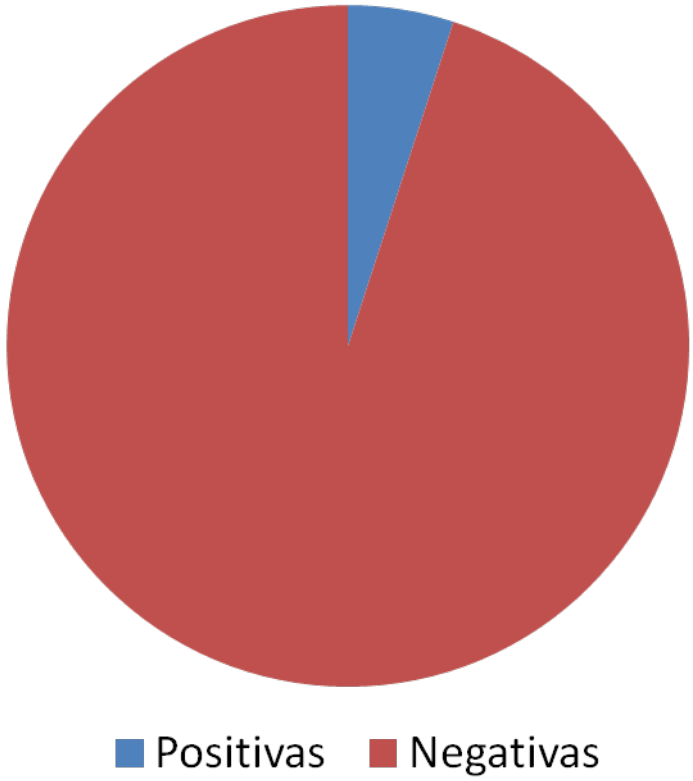


Opiniones de EFSA

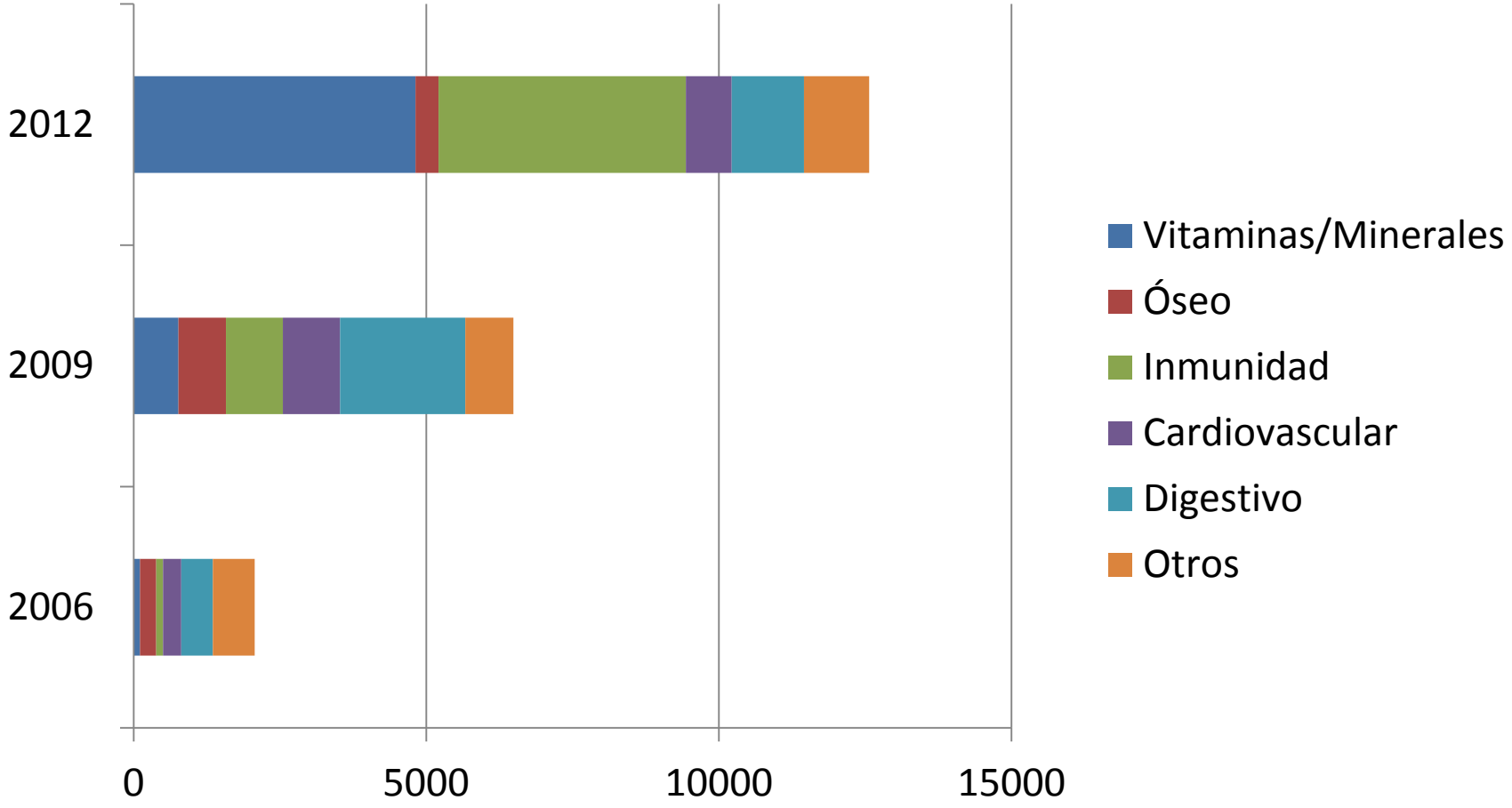
Todas las aplicaciones

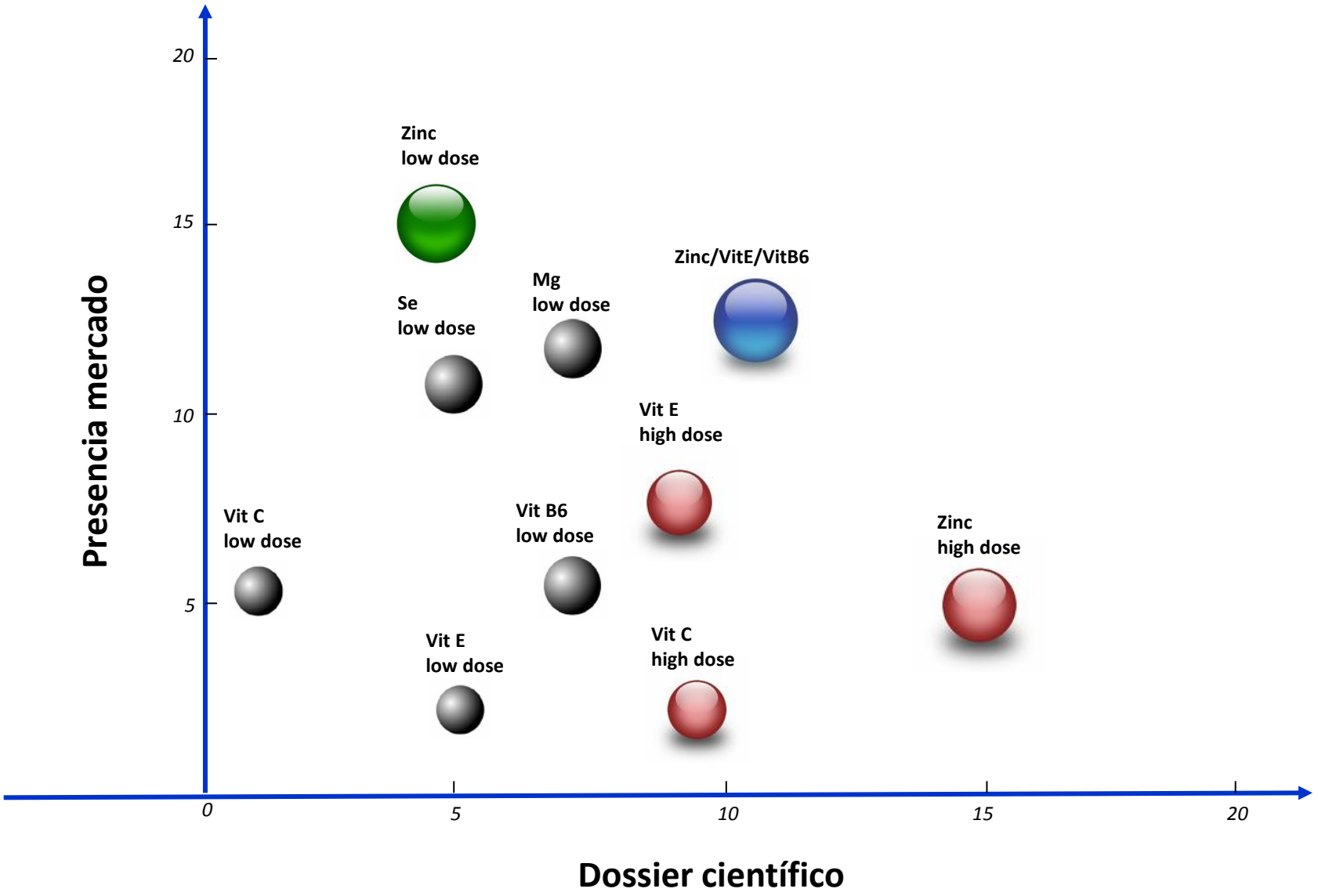


Excepto vitaminas y minerales



El futuro de los claims?
(Claims en productos lanzados mundialmente)




Presencia mercado
20
15
10
5
0
5
10
15
20
Dossier científico
Zinc
low dose
Se
low dose
Mg
low dose
Zinc/VitE/VitB6
Vit E
high dose
Vit C
low dose
Vit B6
low dose
Zinc
high dose
Vit E
low dose
Vit C
high dose

Opiniones de EFSA

Conclusión EFSA	Causa/Efecto	Evaluación científica	GASE (Generally Accepted Scientific Evidence)
Categoría I	Establecida	Concluyente	Sí
Categoría II	Insuficiente	No concluyente	No
Categoría III	No establecida	Limitada	No

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to **zinc** and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006	The Panel considers that the claim **"prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity"** is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. **The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**

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European Food Safety Authority

EFSA Journal 2011;9(6):2169

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from EJP Pharmaceutical ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath. The Panel considers that the proposed claim is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006. © European Food Safety Authority, 2011

KEY WORDS

Zinc, bad breath, health claims.

[1] On request from the Competent Authority of Denmark following an application by EJP Pharmaceutical ApS, Question No EFSA-Q-2010-01092, adopted on 13 May 2011.

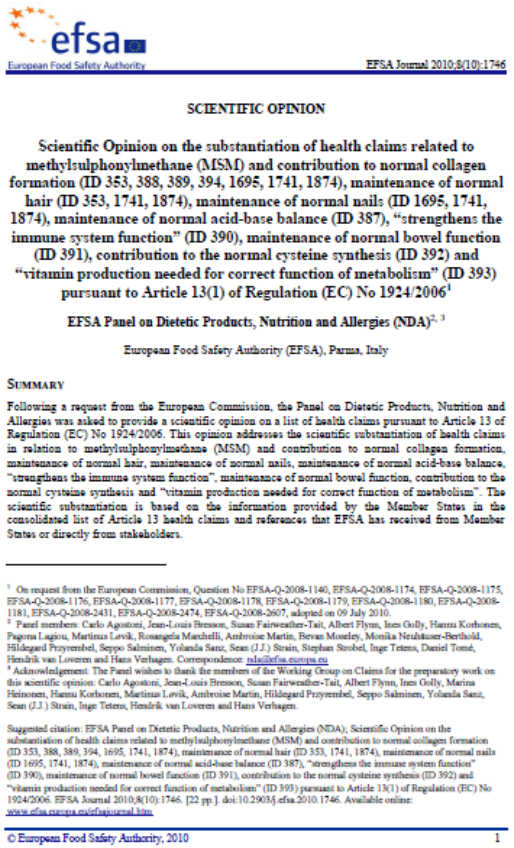
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2169. [7 pp.]. doi:10.2903/j.efsa.2011.2169. Available online: www.efsa.europa.eu/efsajournal

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **methylsulphonylmethane (MSM)** and contribution to normal collagen formation (ID 353, 388, 389, 394, 1695, 1741, 1874), maintenance of normal hair (ID 353, 1741, 1874), maintenance of normal nails (ID 1695, 1741, 1874), maintenance of normal acid-base balance (ID 387), "strengthens the immune system function" (ID 390), maintenance of normal bowel function (ID 391), contribution to the normal cysteine synthesis (ID 392) and "vitamin production needed for correct function of metabolism" (ID 393) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	**"Vitamin production needed for correct function of metabolism"** The claimed effect is "metabolism of vitamins". The target population is assumed to be the general population. In the context of the proposed wording and the clarifications provided by Member States, the Panel notes that the claim refers to "vitamin production needed for correct function of metabolism" and "supports the production of vitamin C, H, B5, B13" which cannot be considered as a health relationship applicable to humans. **The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**



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EFSA Journal 2010;8(10):1746

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to methylsulphonylmethane (MSM) and contribution to normal collagen formation (ID 353, 388, 389, 394, 1695, 1741, 1874), maintenance of normal hair (ID 353, 1741, 1874), maintenance of normal nails (ID 1695, 1741, 1874), maintenance of normal acid-base balance (ID 387), "strengthens the immune system function" (ID 390), maintenance of normal bowel function (ID 391), contribution to the normal cysteine synthesis (ID 392) and "vitamin production needed for correct function of metabolism" (ID 393) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to methylsulphonylmethane (MSM) and contribution to normal collagen formation, maintenance of normal hair, maintenance of normal nails, maintenance of normal acid-base balance, "strengthens the immune system function", maintenance of normal bowel function, contribution to the normal cysteine synthesis and "vitamin production needed for correct function of metabolism". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

[1] On request from the European Commission, Question No EFSA-Q-2008-1140, EFSA-Q-2008-1174, EFSA-Q-2008-1175, EFSA-Q-2008-1176, EFSA-Q-2008-1177, EFSA-Q-2008-1178, EFSA-Q-2008-1179, EFSA-Q-2008-1180, EFSA-Q-2008-1181, EFSA-Q-2008-2431, EFSA-Q-2008-2474, EFSA-Q-2008-2607, adopted on 09 July 2010.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Ströbel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **gamma linolenic acid (GLA)** and maintenance of normal blood LDL cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The claimed effect is **"function of the cell membrane"**. The target population is assumed to be the general population. The Panel notes that several properties of cell membranes have been mentioned in the proposed wordings and that a specific effect related to the function of cell membranes has not been identified. **The Panel considers that the claim is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.** **Maintenance of normal structure, elasticity and appearance of the skin** The claimed effects are "helps to maintain elasticity, tenderness and health of skin, structure and function of skin and mucous membrane", and "membranes cell structure". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of the normal structure, elasticity and appearance of the skin. **The Panel considers that the claims do not refer to a function of the body as required by Regulation (EC) No 1924/2006.**

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European Food Safety Authority
EFSA Journal 2011;9(4):2059

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to gamma-linolenic acid and maintenance of normal blood LDL-cholesterol concentrations, maintenance of normal blood pressure, reduction of menstrual discomfort, contribution to normal cognitive function, maintenance of the barrier function of the skin, "function of the cell membrane", maintenance of normal structure, elasticity and appearance of the skin, and "anti-inflammatory properties". The scientific substantiation is based on the information provided by the Member States

[1] On request from the European Commission, Question No EFSA-Q-2008-1282, EFSA-Q-2008-1286, EFSA-Q-2008-1378, EFSA-Q-2008-1426, EFSA-Q-2008-1427, EFSA-Q-2008-1463, EFSA-Q-2008-2291, EFSA-Q-2008-2502, EFSA-Q-2008-2503, EFSA-Q-2008-2506, EFSA-Q-2008-2508, EFSA-Q-2008-2736, EFSA-Q-2008-2798, EFSA-Q-2008-3393, EFSA-Q-2008-3394, EFSA-Q-2008-3395, EFSA-Q-2010-00249, EFSA-Q-2010-00405, EFSA-Q-2010-00406, EFSA-Q-2010-00407, adopted on 28 January 2011.

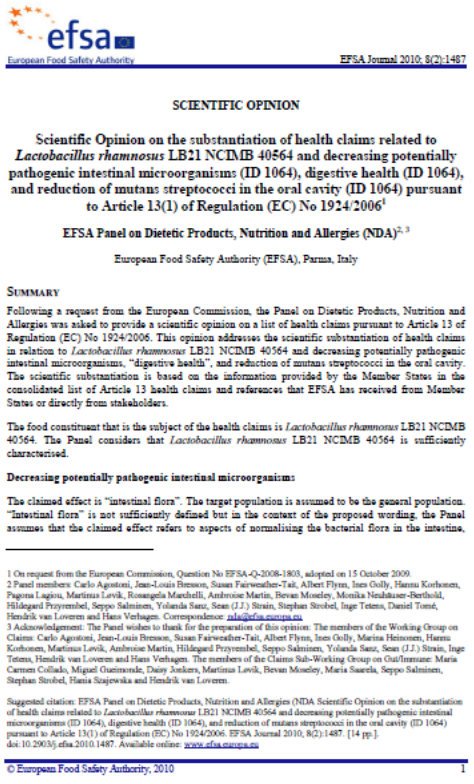
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Martina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2059. [27 pp.]. doi:10.2903/j.efsa.2011.2059. Available online: www.efsa.europa.eu/efsajournal

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **Lactobacillus rhamnosus LB21 NCIMB 40564** and decreasing potentially pathogenic intestinal microorganisms (ID 1064), digestive health (ID 1064), and reduction of mutans streptococci in the oral cavity (ID 1064) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The claimed effect **"digestive health"** is not sufficiently defined. In the context of the proposed wording ('supporting gastrointestinal conditions during antibiotic treatment') and from the references provided, the Panel assumes that the claimed effect relates to acute diarrhoea associated with antibiotic treatment, and that the target group is subjects receiving antibiotic treatment under medical supervision. **The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**



efsa
European Food Safety Authority
EFSA Journal 2010; 8(2):1487

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to *Lactobacillus rhamnosus* LB21 NCIMB 40564 and decreasing potentially pathogenic intestinal microorganisms (ID 1064), digestive health (ID 1064), and reduction of mutans streptococci in the oral cavity (ID 1064) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to *Lactobacillus rhamnosus* LB21 NCIMB 40564 and decreasing potentially pathogenic intestinal microorganisms, "digestive health", and reduction of mutans streptococci in the oral cavity. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is *Lactobacillus rhamnosus* LB21 NCIMB 40564. The Panel considers that *Lactobacillus rhamnosus* LB21 NCIMB 40564 is sufficiently characterised.

Decreasing potentially pathogenic intestinal microorganisms

The claimed effect is "intestinal flora". The target population is assumed to be the general population. "Intestinal flora" is not sufficiently defined but in the context of the proposed wording, the Panel assumes that the claimed effect refers to aspects of normalising the bacterial flora in the intestine.

1 On request from the European Commission, Question No EFSA-Q-2008-1803, adopted on 15 October 2009.
2 Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu
3 Acknowledgement: The Panel wishes to thank for the preparation of this opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Stephan Strobel, Hania Szajewska and Hendrik van Loveren.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Scientific Opinion on the substantiation of health claims related to *Lactobacillus rhamnosus* LB21 NCIMB 40564 and decreasing potentially pathogenic intestinal microorganisms (ID 1064), digestive health (ID 1064), and reduction of mutans streptococci in the oral cavity (ID 1064) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010; 8(2):1487. [14 pp.]. doi:10.2903/j.efsa.2010.1487. Available online: www.efsa.europa.eu

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **various food(s)/food constituent(s)** claiming an increase in renal water elimination, “kidneys health”, “urinary health”, “bladder health”, “health of lower urinary tract”, “blood health”, “elimination”, “urinary system benefits” and/or “supports/promotes the excretory function of the kidney”, and treatment/prevention of renal gravel/kidney stones and urinary tract infections pursuant to Article 13(1) of Regulation (EC) No 1924/2006	**Treatment/prevention of renal gravel/kidney stones and urinary tract infections** The claimed effects are “système urinaire, diurétique, anti-inflammatoire des voies urinaires, prévention des calculs rénaux” and “health of urinary tract”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect is related to the treatment/prevention of renal gravel/kidney stones and urinary tract infections. **The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**

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EFSA Journal 2010;8(10):1742

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming an increase in renal water elimination, “kidneys health”, “urinary health”, “bladder health”, “health of lower urinary tract”, “blood health”, “elimination”, “urinary system benefits” and/or “supports/promotes the excretory function of the kidney”, and treatment/prevention of renal gravel/kidney stones and urinary tract infections pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

[1] On request from the European Commission, Question No EFSA-Q-2008-1927, EFSA-Q-2008-1970, EFSA-Q-2008-2751, EFSA-Q-2008-2767, EFSA-Q-2008-2779, EFSA-Q-2008-2791, EFSA-Q-2008-2841, EFSA-Q-2008-2866, EFSA-Q-2008-2927, EFSA-Q-2008-2932, EFSA-Q-2008-2933, EFSA-Q-2008-2940, EFSA-Q-2008-2947, EFSA-Q-2008-2950, EFSA-Q-2008-2951, EFSA-Q-2008-2955, EFSA-Q-2008-2961, EFSA-Q-2008-2966, EFSA-Q-2008-2986, EFSA-Q-2008-2990, EFSA-Q-2008-2999, EFSA-Q-2008-3006, EFSA-Q-2008-3008, EFSA-Q-2008-3009, EFSA-Q-2008-3013, EFSA-Q-2008-3018, EFSA-Q-2008-3029, EFSA-Q-2008-3031, EFSA-Q-2008-3048, EFSA-Q-2008-3052, EFSA-Q-2008-3055, EFSA-Q-2008-3059, EFSA-Q-2008-3063, EFSA-Q-2008-3071, EFSA-Q-2008-3079, EFSA-Q-2008-3085, EFSA-Q-2008-3088, EFSA-Q-2008-3165, EFSA-Q-2008-3261, EFSA-Q-2008-3264, EFSA-Q-2008-3274, EFSA-Q-2008-3300, EFSA-Q-2008-3329, EFSA-Q-2008-3361, EFSA-Q-2008-3410, EFSA-Q-2008-3424, EFSA-Q-2008-3434, EFSA-Q-2008-3437, EFSA-Q-2008-3438, EFSA-Q-2008-3441, EFSA-Q-2008-3448, EFSA-Q-2008-3472, EFSA-Q-2008-3473, EFSA-Q-2008-3475, EFSA-Q-2008-3498, EFSA-Q-2008-3500, EFSA-Q-2008-3507, EFSA-Q-2008-3513, EFSA-Q-2008-3515, EFSA-Q-2008-3517, EFSA-Q-2008-3518, EFSA-Q-2008-3520, EFSA-Q-2008-3549, EFSA-Q-2008-3963, EFSA-Q-2008-3971, EFSA-Q-2008-3982, EFSA-Q-2008-3995, EFSA-Q-2008-4005, EFSA-Q-2008-4091, EFSA-Q-2008-4097, EFSA-Q-2008-4126, EFSA-Q-2008-4133, EFSA-Q-2008-4134, EFSA-Q-2008-4139, EFSA-Q-2008-4146, EFSA-Q-2008-4188, EFSA-Q-2008-4219, EFSA-Q-2008-4242, EFSA-Q-2008-4245, EFSA-Q-2008-4268, EFSA-Q-2008-4274, EFSA-Q-2008-4296, EFSA-Q-2008-4327, EFSA-Q-2008-4335, EFSA-Q-2008-4345, EFSA-Q-2008-4386, EFSA-Q-2008-4406, EFSA-Q-2008-4416, EFSA-Q-2008-4458, EFSA-Q-2008-4477, EFSA-Q-2008-4481, EFSA-Q-2008-4492, EFSA-Q-2008-4502, EFSA-Q-2008-4526, EFSA-Q-2008-4540, EFSA-Q-2008-4544, EFSA-Q-2008-4585, EFSA-Q-2008-4594, EFSA-Q-2008-4605, EFSA-Q-2008-4609, EFSA-Q-2008-4628, EFSA-Q-2008-4631, EFSA-Q-2008-4645, EFSA-Q-2008-4681, EFSA-Q-2008-4711, EFSA-Q-2008-4752, EFSA-Q-2008-4835, EFSA-Q-2008-4838, EFSA-Q-2008-4889, EFSA-Q-2008-4935, EFSA-Q-2010-00267, EFSA-Q-2010-00300, EFSA-Q-2010-00306, EFSA-Q-2010-00310, EFSA-Q-2010-00385, EFSA-Q-2010-00411, EFSA-Q-2010-00442, EFSA-Q-2010-00445, EFSA-Q-2010-00459, EFSA-Q-2010-00468, EFSA-Q-2010-00471, EFSA-Q-2010-00486, EFSA-Q-2010-00516, EFSA-Q-2010-00518, EFSA-Q-2010-00552, adopted on 09 July 2010.

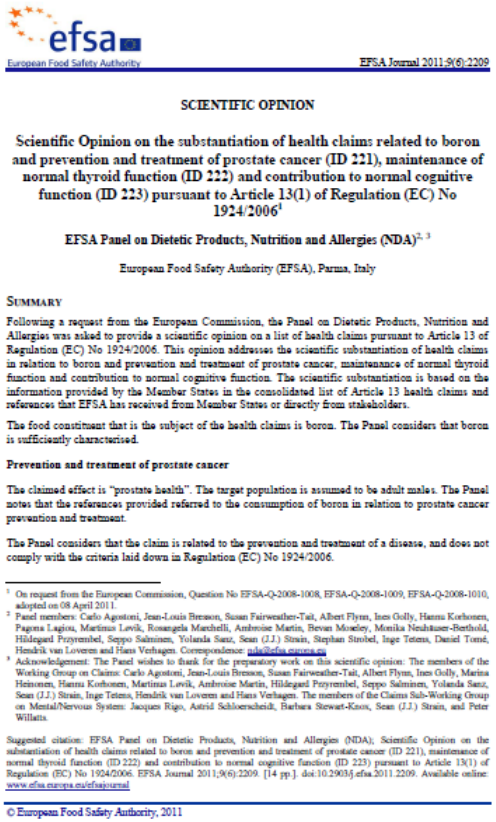
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming an increase in renal water elimination, “kidneys health”, “urinary health”, “bladder health”, “health of lower urinary tract”, “blood health”, “elimination”, “urinary system benefits” and/or “supports/promotes the excretory function of the kidney”, and treatment/prevention of renal gravel/kidney stones and urinary tract infections pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1742. [49 pp.]. doi:10.2903/j.efsa.2010.1742. Available online: www.efsa.europa.eu/efsajournal.htm

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **boron** and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	Prevention and treatment of prostate cancer The claimed effect is **"prostate health"**. The target population is assumed to be adult males. The Panel notes that the references provided referred to the consumption of boron in relation to prostate cancer prevention and treatment. **The Panel considers that the claim is related to the prevention and treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**



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European Food Safety Authority
EFSA Journal 2011;9(6):2209

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to boron and prevention and treatment of prostate cancer, maintenance of normal thyroid function and contribution to normal cognitive function. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is boron. The Panel considers that boron is sufficiently characterised.

Prevention and treatment of prostate cancer

The claimed effect is "prostate health". The target population is assumed to be adult males. The Panel notes that the references provided referred to the consumption of boron in relation to prostate cancer prevention and treatment.

The Panel considers that the claim is related to the prevention and treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

[1] On request from the European Commission, Question No EFSA-Q-2008-1008, EFSA-Q-2008-1009, EFSA-Q-2008-1010, adopted on 08 April 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2209. [14 pp.]. doi:10.2903/j.efsa.2011.2209. Available online: www.efsa.europa.eu/efsajournal

Producto Medicinal

Toda sustancia o combinación de sustancias que se **presente como** poseedoras de **propiedades para el Tratamiento o prevención de enfermedades en seres humanos, o**

Toda sustancia o combinación de sustancia que pueda **usarse en, o administrarse a seres humanos con el fin de restaurar, corregir corregir o modificar las funciones fisiológicas** ejerciendo una acción farmacológica, inmunológica, o de establecer un ´diagnóstico médico

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to **Vitis vinifera L. seeds extract** and "helps to decrease swollen legs" pursuant to Article 13(5) of Regulation (EC) No 1924/2006	The Panel considers that the **reduction of peripheral oedema in the context of chronic clinical conditions** is a **therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006**.

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European Food Safety Authority
EFSA Journal 2012;10(12):2997

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and "helps to decrease swollen legs" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Vitis vinifera* L. seeds extract and "helps to decrease swollen legs". The Panel considers that the food constituent which is the subject of the health claim is sufficiently characterised. Upon EFSA's request for clarification, the applicant stated that the claimed effect was "helps to decrease swollen legs", and that the beneficial physiological effect could be related to "helps to refine legs". In the context of the references provided for the scientific substantiation of the claim, and in particular of the human intervention study which was conducted with the food constituent that is the subject of the health claim, the Panel notes that the claim refers to the reduction of peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) where the reduction of peripheral oedema is a therapeutic target for the treatment of the condition. The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Vitis vinifera, swollen legs, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00388, adopted on 28 November 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Dominique Turck, Hendrik van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and "helps to decrease swollen legs" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(12):2997. [8 pp.]. doi:10.2903/j.efsa.2012.2997. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to **EffEXT**™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.	Scientific Opinion on the substantiation of a health claim related to EffEXT™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 The Panel considers that the **reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis** is a **therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**

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EFSA Journal 2012;10(9):2889

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Eff_{EXT}™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Eff_{EXT}™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel considers that Eff_{EXT}™, which is standardised pure krill oil, is sufficiently characterised. The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel notes that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein. Whether or not reduction of inflammatory markers is considered beneficial depends on the context in which a claim is made. In the context of the study provided, the Panel notes that the claim refers to diseases such as osteoarthritis or rheumatoid arthritis, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease. The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Eff_{EXT}™, krill oil, joints, inflammation, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00386, adopted on 13 September 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Eff_{EXT}™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(9):2889. [6 pp.]. doi:10.2903/j.efsa.2012.2889. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **gamma linolenic acid (GLA)** and maintenance of normal blood LDL cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	**The Panel considers that the reduction of inflammation in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition.**

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EFSA Journal 2011;9(4):2059

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to gamma-linolenic acid and maintenance of normal blood LDL-cholesterol concentrations, maintenance of normal blood pressure, reduction of menstrual discomfort, contribution to normal cognitive function, maintenance of the barrier function of the skin, "function of the cell membrane", maintenance of normal structure, elasticity and appearance of the skin, and "anti-inflammatory properties". The scientific substantiation is based on the information provided by the Member States

[1] On request from the European Commission, Question No EFSA-Q-2008-1282, EFSA-Q-2008-1286, EFSA-Q-2008-1378, EFSA-Q-2008-1426, EFSA-Q-2008-1427, EFSA-Q-2008-1463, EFSA-Q-2008-2291, EFSA-Q-2008-2502, EFSA-Q-2008-2503, EFSA-Q-2008-2506, EFSA-Q-2008-2508, EFSA-Q-2008-2736, EFSA-Q-2008-2798, EFSA-Q-2008-3393, EFSA-Q-2008-3394, EFSA-Q-2008-3395, EFSA-Q-2010-00249, EFSA-Q-2010-00405, EFSA-Q-2010-00406, EFSA-Q-2010-00407, adopted on 28 January 2011.

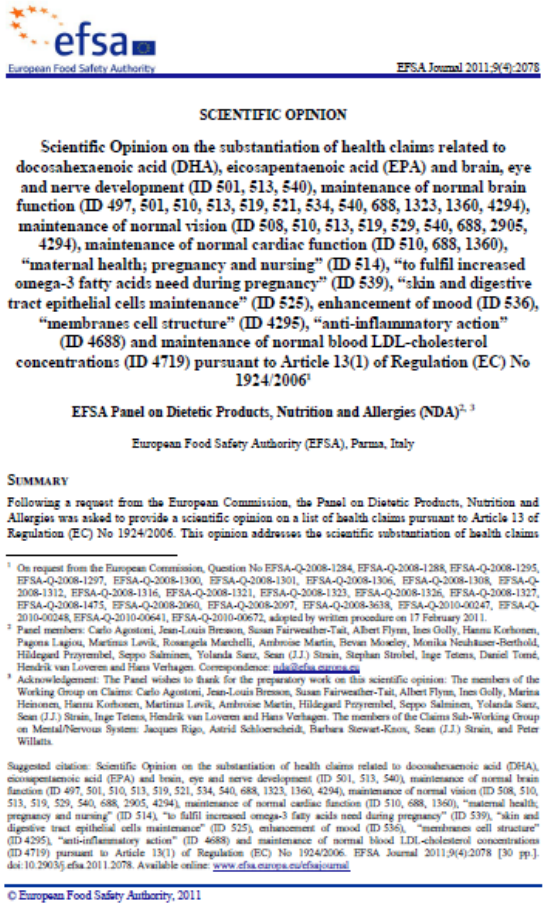
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2059. [27 pp.]. doi:10.2903/j.efsa.2011.2059. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to **docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA)** and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), "maternal health; pregnancy and nursing" (ID 514), "to fulfil increased omega-3 fatty acids need during pregnancy" (ID 539), "skin and digestive tract epithelial cells maintenance" (ID 525), enhancement of mood (ID 536), "membranes cell structure" (ID 4295), "anti-inflammatory action" (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	**The Panel considers that the reduction of inflammation in the context of inflammatory diseases is a therapeutic target for the treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.**



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EFSA Journal 2011;9(4):2078

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), "maternal health; pregnancy and nursing" (ID 514), "to fulfil increased omega-3 fatty acids need during pregnancy" (ID 539), "skin and digestive tract epithelial cells maintenance" (ID 525), enhancement of mood (ID 536), "membranes cell structure" (ID 4295), "anti-inflammatory action" (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims

[1] On request from the European Commission, Question No EFSA-Q-2008-1284, EFSA-Q-2008-1288, EFSA-Q-2008-1295, EFSA-Q-2008-1297, EFSA-Q-2008-1300, EFSA-Q-2008-1301, EFSA-Q-2008-1306, EFSA-Q-2008-1308, EFSA-Q-2008-1312, EFSA-Q-2008-1316, EFSA-Q-2008-1321, EFSA-Q-2008-1323, EFSA-Q-2008-1326, EFSA-Q-2008-1327, EFSA-Q-2008-1475, EFSA-Q-2008-2060, EFSA-Q-2008-2097, EFSA-Q-2008-3638, EFSA-Q-2010-00247, EFSA-Q-2010-00248, EFSA-Q-2010-00641, EFSA-Q-2010-00672, adopted by written procedure on 17 February 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), "maternal health; pregnancy and nursing" (ID 514), "to fulfil increased omega-3 fatty acids need during pregnancy" (ID 539), "skin and digestive tract epithelial cells maintenance" (ID 525), enhancement of mood (ID 536), "membranes cell structure" (ID 4295), "anti-inflammatory action" (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2078 [30 pp.]. doi:10.2903/j.efsa.2011.2078. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
"Scientific Opinion on the substantiation of health claims related to **polyphenols in olive** and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006"	**The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006**

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EFSA Journal 2011;9(4):2033

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to polyphenols in olive and protection of LDL particles from oxidative damage, maintenance of normal blood HDL-cholesterol concentrations, maintenance of normal blood pressure, "anti-inflammatory properties", "contributes to the upper respiratory tract health", "can help to maintain a normal function of gastrointestinal tract", and "contributes to body defences against external agents". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

[1] On request from the European Commission, Question No EFSA-Q-2008-2070, EFSA-Q-2008-2374, EFSA-Q-2008-2375, EFSA-Q-2008-2432, EFSA-Q-2008-2615, EFSA-Q-2008-3598, EFSA-Q-2008-4195, EFSA-Q-2008-4196, EFSA-Q-2008-4498, EFSA-Q-2008-4500, adopted on 12 November 2010.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2033 [25 pp.]. doi:10.2903/j.efsa.2011.2033. Available online: www.efsa.europa.eu/efsajournal

Declaraciones de Reducción de Riesgo de Enfermedad [Art. 14(1)(a)]	Declaraciones Medicinales
Referencia a la reducción de un factor de riesgo de desarrollo de la enfermedad	Referencia a la reducción del riesgo de desarrollo de la enfermedad
No relación directa causa-efecto	Relación directa causa-efecto
Futuro / Efecto benéfico a largo plazo (enfoque basado en la nutrición)	Inmediato/ Efecto benéfico a corto plazo
Población objeto- sana	Población objeto- diagnosticada

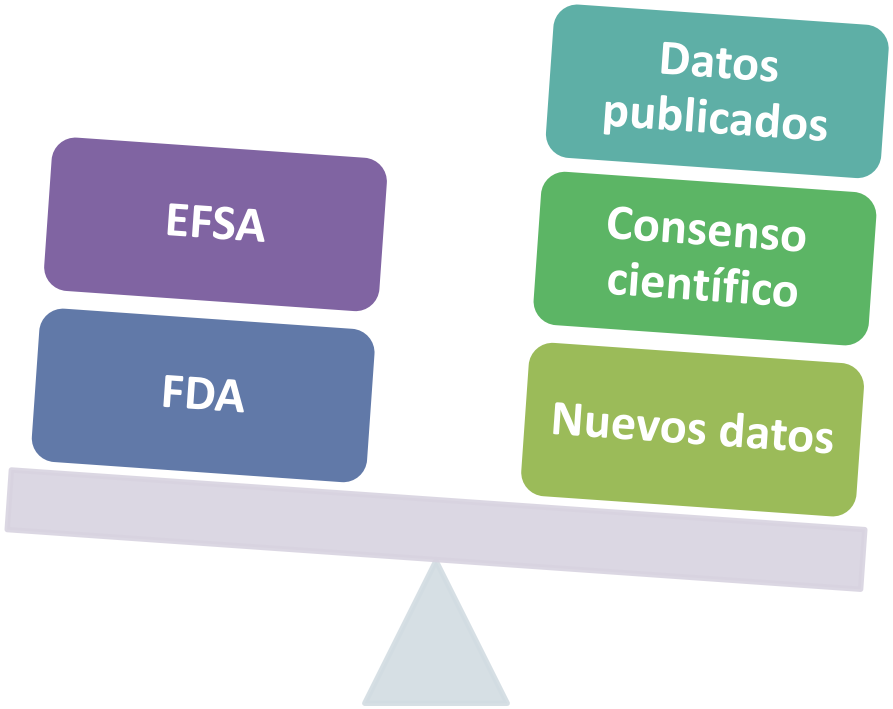
#1	Comprobar el estatus de la *claim* en el Registro de la Comisión y de EFSA
#2	Comprobar el status de las marcas que sugieren un beneficio
#3	La declaración debe estar relacionada con el nutriente o la sustancia
#4	Comprobar que el *wording* utilizado esté dentro del margen de flexibilidad
#5	No sugerir que la salud podría verse afectada por no consumir el producto promocionado
#6	No exagerar los beneficios ni hacer promesas, sino ser moderados en su descripción
#7	No sugerir que los productos poseen propiedades medicinales
#8	Prestar atención a la publicidad sobre el proceso de producción
#9	Atención a las *claims* cosméticas, pueden ser consideradas de propiedades saludables
#10	Las declaraciones de salud generales [10(3)] deben ir acompañadas de una declaración específica
#11	No hacer referencia a estudios clínicos cuando la *claim* ha sido rechazada
#12	Las declaraciones de reducción de riesgo de enfermedad no se pueden utilizar hasta que se aprueben caso por caso
#13	No unificar dos o más *claims* si los beneficios de las mismas han sido aprobados por separado

Si queremos hacer un "Health Claim" por dónde empezamos?

Iniciando el camino

Claims aprobados

Evidencia



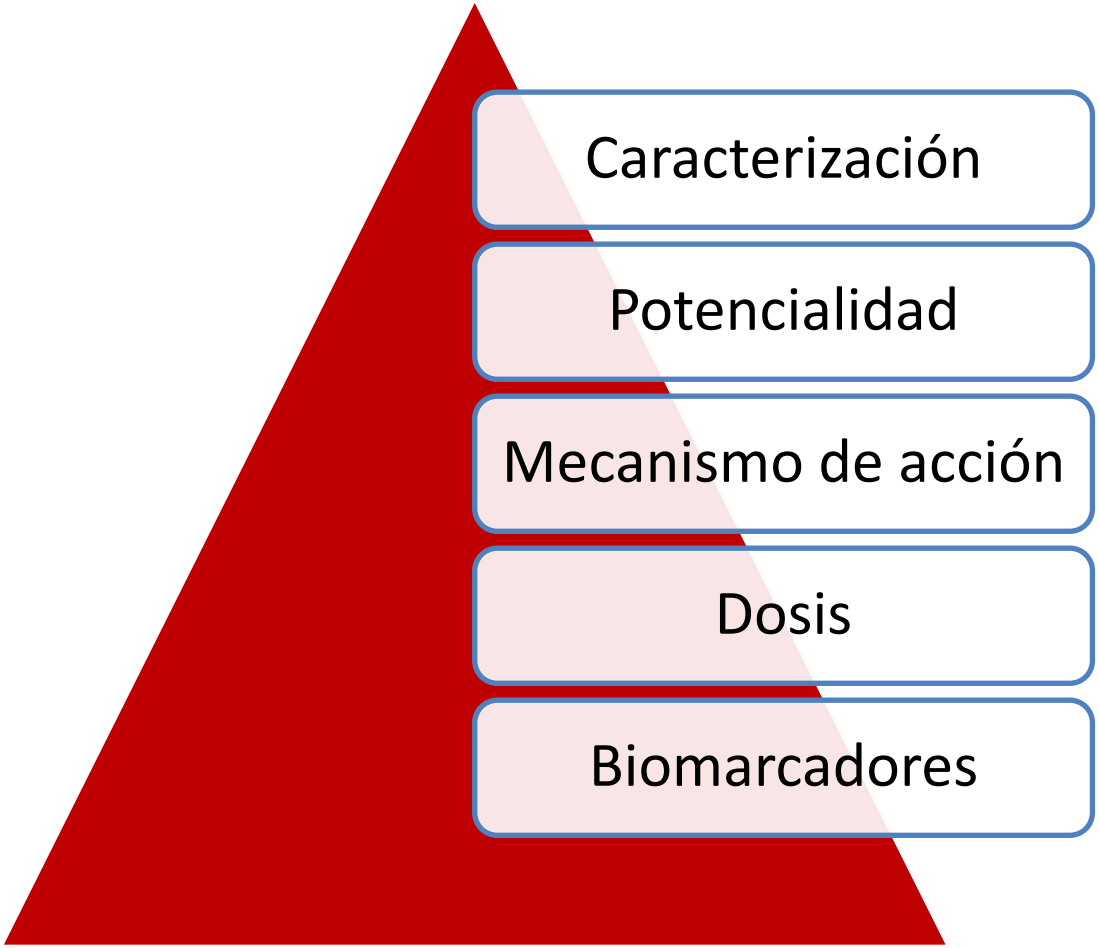
Preliminares

1
- Validación preliminar del claim en otros Reguladores.
- Repasar la evidencia existente.

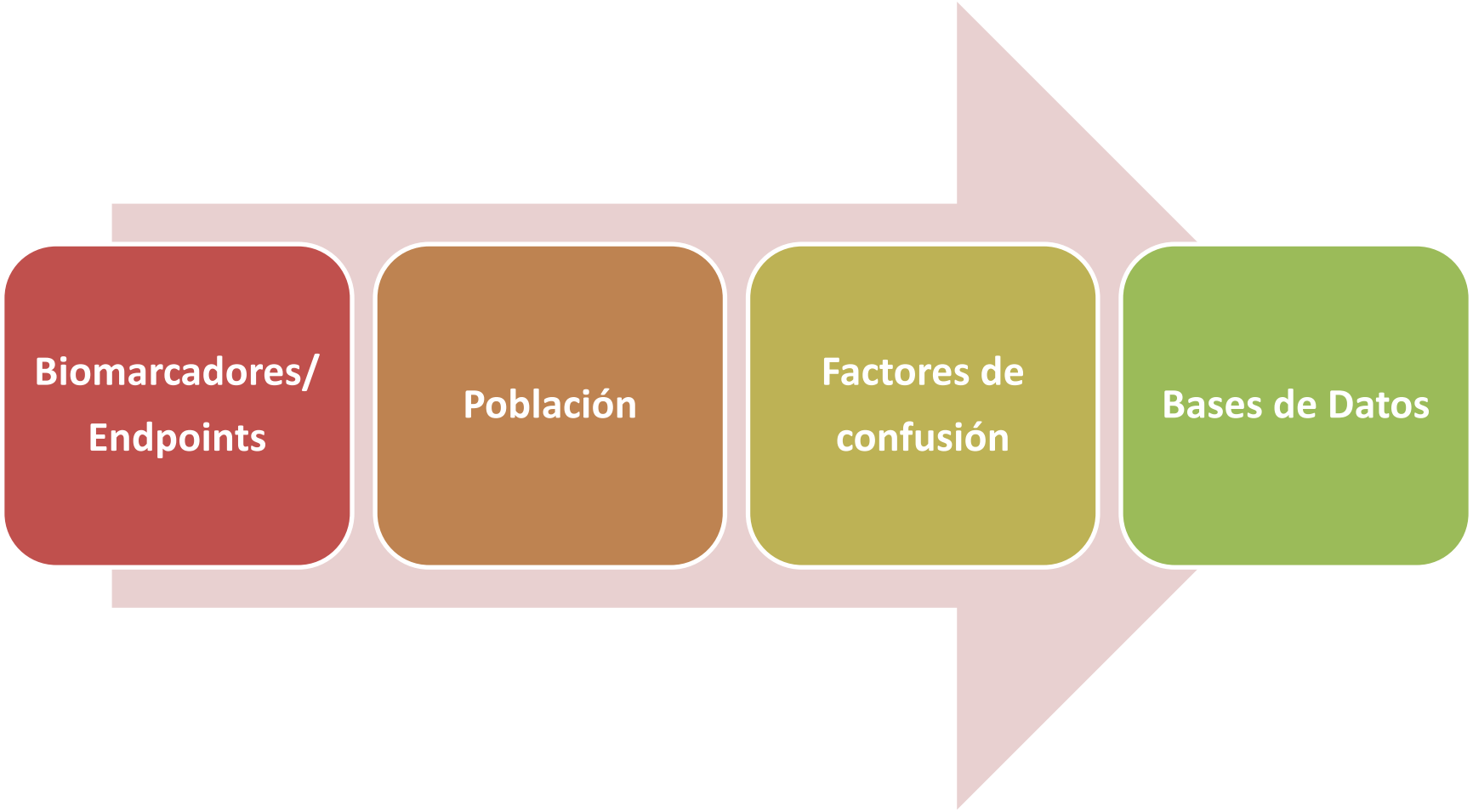
2
- Estudiar la cantidad y calidad de los estudios necesarios.
- Hacer SWOT referente a los estudios requeridos.

3
- Revisar la estrategia.
- Empezar ……

Estudios preclínicos



Evidencia en humanos



Finalmente objetivar …

Constituyente

- Ingrediente bioactivo
- Relación constituyente/ claim
- Fabricación
- Estabilidad
- Biodisponibilidad
- Estudios

Claim

- Propuesta de wording para el claim
- Target
- Dosis
- Precauciones

Muchas gracias!!!!!